



**ASPR**

# American College of Clinical Pharmacy Live Q&A Webinar

**CAPT William E Kelly, PharmD, MA, MS, USN  
Federal COVID-19 Therapeutics Team**

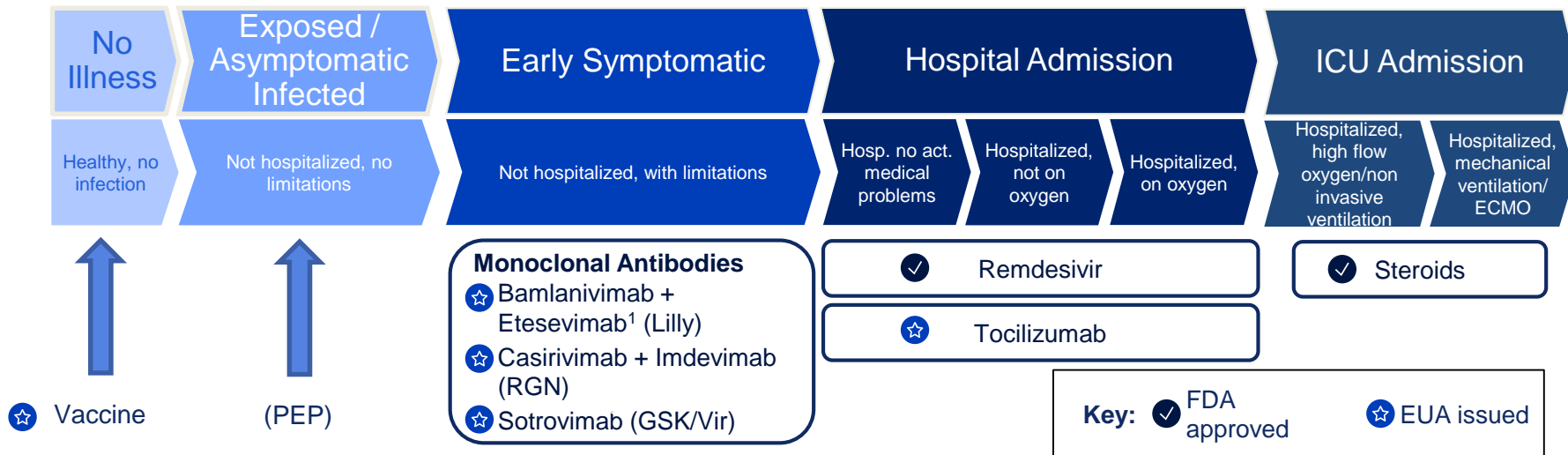
**July 22<sup>nd</sup>, 2021**

Unclassified/For Public Use

# My Deployment



# Summary of COVID-19 Therapeutics



1. National shipment pause due to variants, as of 07/8/2021

# Bottom Line: Monoclonal antibodies 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 (within 10 days) in disease course**
- Early evidence appears to suggest promise of mAb products in outpatient settings; products ([bamlanivimab/etesevimab](#)<sup>1</sup> and REGEN-COV([casirivimab/imdevimab](#))) **reduce the relative risk of hospitalizations by up to 70% in high-risk patients**
- **Immunocompromised Patients are Important Focus**

1. National shipment pause due to variants, as of 06/25/2021

## Treatment eligibility

- May be eligible to receive treatment if the patient (12 years of age or older and weighing at least 40 kg):
  - Has mild to moderate COVID-19 that has tested **positive** with direct viral testing,
  - Is within **10 days** of symptom onset, **and**
  - Is at **high risk** of progression to severe COVID-19 including hospitalization or death

### *Clinical Judgement*

- Please reference EUA factsheets for specific treatment guidelines and detailed definitions of high-risk patients
  - [Bamlanivimab /Etesevimab<sup>1</sup>](#)
  - [Casirivimab /Imdevimab](#)

1. National shipment pause due to variants, as of 06/25/2021

# USG role in distribution of COVID-19 mAbs

**Three outpatient mAbs have been granted EUA for the treatment of COVID-19** based on their potential to reduce progression to severe disease and hospitalization in high-risk patients.

HHS/ASPR has oversight responsibility for the fair and transparent allocation and distribution of two of these therapies.<sup>1</sup>

Uptake of therapies can have a significant public health impact

**Our goal:** Facilitate the effective use of monoclonal antibody therapeutics to reduce COVID-19 hospitalizations

1. National shipment pause due to variants, as of 06/25/2021

## USG-procured therapies are provided at no-cost

- Health care providers can order product directly through the distributor AmerisourceBergen at no cost; information on ordering available at [phe.gov](https://phe.gov)
- CMS reimbursement rates have recently been increased to **\$450** for most outpatient settings; and **\$750** when administered in a patient's home
- Additional information on reimbursement can be found at [Monoclonal Antibody COVID-19 Infusion | CMS](#)
- Treatment options for uninsured available through [HRSA](#)

# Federal Operational Issues: Four Pillars of Equitable Access

- I. Home administration (infusion)
- II. Home delivery (whatever means necessary)
- III. Rapid test to treat (patient navigators)
- IV. Rapid response (field-ready teams that can be pre-positioned)

## Information Sharing: Best practices and resources

- USG engages with medical, professional and/or advocacy societies to share best practices
- Best practices and testimonials available at
  - Available at – <https://combatcovid.hhs.gov/hcp/videos-monoclonal-antibodies>
- Additional information and resources available at [phe.gov/combatcovid.hhs.gov](https://phe.gov/combatcovid.hhs.gov)

# Q&A Session

Pharmacists connect people who need their medicine with vital medications. Officers from the U.S. Public Health Service prepare medications for people who are quarantined on Travis Air Force Base following the #COVID19 pandemic.



8:00 PM · Mar 17, 2020 · Sprout Social

## CDR Diana Solana-Sodeinde, Pharm.D. U.S. Public Health Service

*My deployment experience  
in March 2020 taking care of Cruise  
Passengers who were quarantined at  
Travis Airforce Base, CA.*

Reference on ASPR media: <https://twitter.com/PHEgov/status/1240065453218816007>



**Thank you!**