Monoclonal Antibodies for COVID-19: A Webinar for the Case Management Society of America (CMSA)

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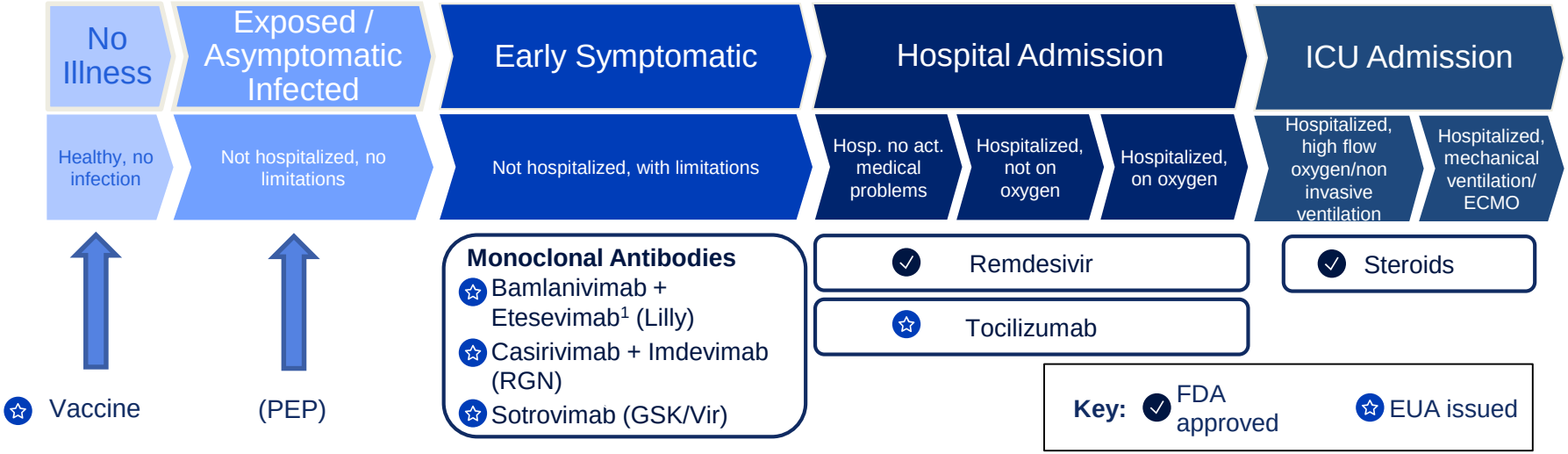
Agenda

- Intro to Monoclonal Antibodies
  - Clinical Use
  - Mechanism of Action
  - Patient Eligibility
- Operational Issues
  - Rapid Testing
  - Current Federal Foci
- Communication and Patient Advocacy

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[1] and REGEN-COV(casirivimab/imdevimab)) **reduce the relative risk of hospitalizations by up to 70% in high-risk patients**
- **Immunocompromised Patients are Important Focus**

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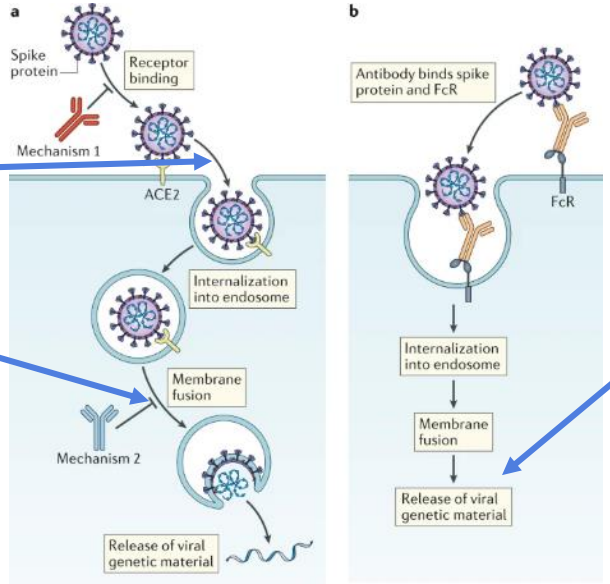
Potential mechanisms for the clinical effects of Monoclonals

a) Bind to Virus

1) Block Cell Uptake

2) Block Membrane Fusion

Impede ability to replicate



b) Bind to Virus

3) Deliver to immune

Destruction

Source: Nature

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[1]
  - Casirivimab /Imdevimab

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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
- 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

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

Federal Operational Issues: Four Pillars of Equitable Access

I. **Home** administration

II. **Home** delivery

III. **Rapid** test to treat

IV. **Rapid** response

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

Asks for community leaders

Promote the awareness of therapies in your local communities

- Share information in local community outlets
- Post information online for individuals to understand that mAbs are available treatment options (neighborhood apps, social media, etc)
- Host outreach events

Understand where treatment locations are in your local community and encourage individuals to seek out mAb treatment

Share experiences to support others in pursuing treatment

- Post information online (blogs, social media, etc)
- Share your experience with HHS/ASPR at COVID19Therapeutics@hhs.gov