COVID-19 Information Update

GPhA / Tracy Dabbs, PharmD and Aji Kim, 4th year pharmacy student / September 2021

Discussion Topics

- FDA approval of Pfizer COVID-19 vaccine
- Review updates on COVID-19 vaccine booster doses
- Discuss COVID-19 vaccine provider agreement
- Provide VMS information for DPH pandemic providers
- Monoclonal antibody overview
  - Introduction
  - REGEN-COV2

CE Information

UAN: 0142-0000-21-039-L01-P/T

CPE hours: .75

Activity type: Knowledge

Target Audience: Pharmacists, Pharmacy Techs

Learning Objectives for Pharmacists

At the completion of this activity, the participant will be able to:

- Describe the expanded access of COVID-19 therapeutics available through the ninth amendment of the Public Readiness and Emergency Preparedness (PREP) Act for pharmacists.
- Discuss the steps associated with the completion of the Georgia Department of Public Health (DPH) vaccine provider agreement.
- State the process associated with the Vaccine Management System (VMS) for DPH pandemic providers.

Learning Objectives for Pharmacy Technicians

At the completion of this activity, the participant will be able to:

- Describe the expanded access for pharmacy technicians to administer COVID-19 therapeutics through the ninth amendment of the Public Readiness and Emergency Preparedness (PREP) Act.
- List the pharmacy technician requirements (e.g., training, certification) for administering COVID-19 therapeutics.
- Discuss roles of the pharmacy technician in assisting the pharmacist with documentation for the Vaccine Management System (VMS).

Delta Variant

- Delta (B.1.617.2) is currently the most predominant COVID variant in Georgia
- The Delta variant is more than two times as contagious as other variants
- The greatest risk of COVID transmission is among unvaccinated people
- COVID vaccines are highly effective at preventing severe disease, hospitalization and death
- High vaccination coverage reduces the spread of COVID and helps prevent new variants from emerging

FDA Approval of COVID Vaccines

- FDA approved Pfizer's COVID vaccine August 23, 2021
- Pfizer vaccine now marketed as **Comirnaty** (koe-mir'-na-tee)
- The approval is for individuals 16 years of age and older
  - Use for Individuals 12 through 15 is authorized by EUA
  - 3rd doses for immunocompromised are authorized by EUA
- Moderna has applied for full FDA-approval of its COVID vaccine for individuals aged 18 years and older
- Johnson & Johnson expects to apply for full approval later this year

7

J&J COVID-19 Vaccine

- J&J COVID-19 vaccine has not been authorized for additional doses or booster doses at this time
- J&J vaccine did not receive EUA until March 2021
- More data is necessary for booster dose information
- Medical experts anticipate those who received J&J would need a booster dose

8

Pfizer/BioNTech COVID-19 Vaccine Approval

- The FDA-approved Pfizer-BioNTech product COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns
- Providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine.
- The Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine

COVID Vaccine Additional Dose

- CDC recommends an additional dose of vaccine to improve response to the initial vaccine series
  - An additional dose of COVID-19 vaccine would be for individuals who might have not mounted enough immunity due to underlying health conditions, medical treatments, or medications
- Additional doses of Pfizer and Moderna have been authorized for certain immunocompromised patients
- The recommendation currently does not include J&J vaccine recipients

Eligibility for Additional Dose

- Individuals receiving active cancer treatment for tumors or cancers of the blood
- Individuals who received an organ transplant and are taking medicine to suppress the immune system
- Individuals who received a stem cell transplant within the last two years or are taking medicine to suppress the immune system
- Individuals with moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Individuals with advanced or untreated HIV infection
- Individuals with actively being treated with high-dose corticosteroids or other drugs that may suppress the immune response
- **NOTE:** Individuals should talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them.

COVID Vaccine Booster Dose

- A booster dose of COVID-19 vaccine is for individuals who have completed a vaccination series but have reduced immunity over time

Pending FDA authorization and ACIP recommendation

- Pfizer and Moderna have requested permission to administer a third dose of their COVID-19 vaccines

COVID-19 Vaccine Provider Agreement

- Updated requirements in the CDC COVID-19 Vaccination Program Provider Agreement
- Providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, the Advisory Committee on Immunization Practices, and the U.S Food and Drug Administration (FDA). This applies to both EUA and FDA approved COVID-19 vaccines
- Use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended

COVID-19 Vaccine Provider Agreement

Violation of the Vaccine Provider Agreement could expose COVID-19 vaccine providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program
- Administration fees may not be reimbursable by payers

Vaccine Management System

Vaccine Management System (VMS) is a secure solution for COVID vaccine that enables vaccine management and data sharing for the State of Georgia on one central platform.

In VMS, DPH users may:

- View vaccine requests
- View provider information
- View manufacturer and vaccine information

VMS

- COVID-19 vaccine providers through DPH will need a VMS account to order COVID-19 vaccine
- Microsoft Office Account requirement
- Questions?
  - Questions should be directed to the Provider Support Call Center at:
    - Phone - 888-920-0165
    - Email - DPH-COVID19vaccine@dph.ga.gov

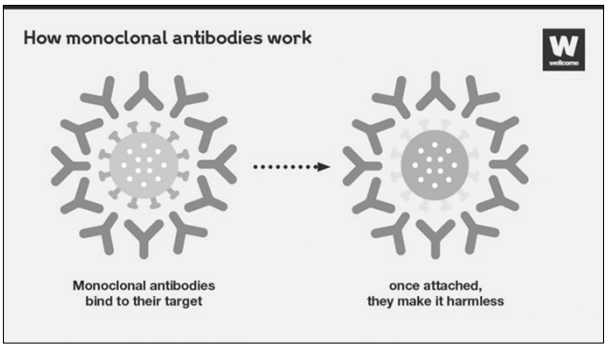
Expanding Access to COVID 19 Therapeutics

HHS PREP Act Declaration: 9th Amendment

- The 9th amendment to the COVID 19 PREP Act Declaration provides liability immunity to and expands the scope of authority for **licensed pharmacists** to order and administer select COVID 19 therapeutics to populations authorized by the FDA and for **pharmacy technicians and pharmacy interns** to administer COVID 19 therapeutics
- An example of a COVID 19 therapeutic would be REGEN-COV, a monoclonal antibody developed by Regeneron

Monoclonal Antibodies

- Man-made proteins that mimic human's immune system's ability to fight off harmful antigens such as viruses
- Antibody circulate throughout the body until they find their specific antigen and attaches to it
- Once attached to the antigen, other parts of immune system comes along and destroy cells that contain the antigen



Monoclonal Antibody Treatment

- The first monoclonal antibody approved by the FDA was the Orthoclone OKT3 (muromonab-CD3) in 1986.
  - Indication: steroid-resistant acute allograft rejection in cardiac and hepatic transplant
- **Before the –mab: source**
  - **-o-mab**: mouse
  - -**xi-mab**: chimeric (human + non-human)
  - **-zi-mab**: humanized (mostly human + part non-human)
  - **-u-mab**: human
- **Before the source: targets**
  - **C(i)**: circulatory system
  - **K(i**): interleukin
  - **L(i)**: immune system
  - **T(u)**: tumor
  - **V(i):** virus

REGEN-COV (casirivimab + imdevimab)

- Authorized under EUA
- **Indication**: COVID-19 post exposure prophylaxis (PEP), COVID-19 mild to moderate treatment
- **Administration**:
  - IV (preferred)
  - Subcutaneous

REGEN-COV Formulations

There are **TWO** different formulations of REGEN-COV:

- Casirivimab and imdevimab co-formulated solution containing two antibodies in a 1:1 ratio in a vial
- Casirivimab and imdevimab available as individual antibody solutions in separate vials, supplied in individual vials, and dose pack.
- The dose pack contains individual vials of casirivimab and imdevimab, configurations that may vary in vial size, strength, and appearance

REGEN-COV (casirivimab + imdevimab)

- Side effects: injection site reactions such as skin redness, irritation sensation, and ecchymosis
- Post exposure prophylaxis with REGEN-COV2 is not a substitute for vaccination against COVID-19
- REGEN-COV2 is not authorized for pre-exposure prophylaxis for prevention of COVID-19
- REGEN-COV2 is not authorized for treatment of severe COVID-19 cases due to unavailable data ex: patients with ventilator

Monoclonal Antibody Access in Georgia

- Currently over 150 locations in Georgia where monoclonal antibody treatment is available

  https://protect-public.hhs.gov/pages/therapeutics-distribution

- Call Center dedicated to questions and information related to mAbs:

  English: 1-877-332-6585

  Spanish: 1-877-366-0310

References

1. https://www.hhs.gov/about/news/2021/08/18/joint-statement-hhs-public-health-and-medical-experts-covid-19-booster-shots.html
2. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
3. https://www.webmd.com/vaccines/covid-19-vaccine/news/20210817/us-to-recommend-covid-vaccine-boosters-8-months
4. https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf
5. https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine