OPTUMRx®

Spikevax™ (COVID-19 vaccine, mRNA) – CDC's ACIP votes to recommend vaccine for adults 18 years of age and older

- On February 4, 2022, the Center for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) met to discuss the FDA approval of Moderna's Spikevax (COVID-19 vaccine, mRNA), for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.
    - The experts reviewed updated data from the original phase 3 trials that supported the emergency use authorization (EUA) as well as real world evidence from post-authorizations of the vaccine.
- Myocarditis: As of January 13, 2022, 164 million doses of Moderna's COVID-19 vaccine have been administered to adults 18 years of age and older. A total of 359 reports of myocarditis have been reported to the Vaccine Adverse Event Reporting System (VAERS).
    - Vaccine-associated myocarditis rates exceeded expected background rates in males 18–49 years and in females 18–29 years (after dose 2 only).
    - Most myocarditis patients were hospitalized (337), and most were discharged home (335).
    - According to the COVID-19 Vaccine Safety Technical (VaST) Work Group, most cases of myocarditis are clinically mild, and data do not suggest new safety concerns regarding Moderna vaccination among persons aged 18 years or older, beyond those previously identified.
- ACIP discussed the epidemiology of COVID-19, effectiveness and safety of the Spikevax vaccine.
    - The ACIP felt the benefits of the vaccine outweighed any risks in adults 18 years of age and older.
- After extensive discussion, ACIP voted unanimously in favor of vaccination with Spikevax COVID-19 vaccine (2-doses, 100 mcg, intramuscularly) for adults 18 years of age and older.
    - This recommendation is for the initial primary series of two doses.

What's Next:

- The CDC's Director will need to sign off on the recommendations of ACIP.
- Currently, the Spikevax vaccine is not available; however, the Moderna COVID-19 vaccine approved under emergency use authorization may be used interchangeably.

Additional Discussion:

- The CDC recommended revised guidance for vaccine administration for moderately or severely immunocompromised individuals through emergency use instructions (EUI):
    - People (ages 12 years and older for Comirnaty and 18 years and older for Spikevax) who are moderately or severely immunocompromised should receive a booster dose at least 3 months after the last (third) dose of an mRNA COVID-19 vaccine. Previously, the booster dose was recommended after 5 months.

Continued . . .

  - People who are moderately or severely immunocompromised should receive an additional dose of a mRNA vaccine at least 28 days after the first dose of the Janssen COVID-19 vaccine and a booster dose at least 2 months after the 2nd dose (for a total of 3 doses).
  - For booster doses, any vaccine may be used; however, mRNA vaccines are preferred.
  - On a case-by-case basis, providers who care for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgement when the benefits of vaccination are deemed to outweigh the potential and unknown risks.
  - CDC's updated clinical guidelines can be found here.

- The CDC also recommended revised guidance for passive antibody products:

  - No recommended deferral period after COVID-19 vaccination.
  - Previously, COVID-19 vaccination was recommended to be deferred for 30 days if product was used for post-exposure prophylaxis, 90 days if product was used for treatment, and there was no guidance for pre-exposure prophylaxis.
  - However, Evusheld™ (tixagevimab/cilgavimab) should be deferred for at least two weeks after vaccination.