Comirnaty® (COVID-19 vaccine, mRNA) – New vaccine approval

- On August 23, 2021, the FDA announced the approval of Pfizer/BioNTech's Comirnaty (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 16 years of age and older.
    - Comirnaty and the EUA-authorized Pfizer-BioNTech COVID-19 vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.
    - The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.
- Comirnaty is the first approved vaccine for the prevention of COVID-19 in the U.S.
- The efficacy of Comirnaty was demonstrated in a randomized, placebo-controlled, observer-blinded study enrolling 36,621 participants 12 years of age and older who did not have evidence of prior infection with SARS-CoV-2.
    - Updated VE in individuals who did not have evidence of prior infection with SARS-CoV-2 and followed for ≥ 4 months after the 2nd dose was 91.1% (95% CI: 88.8, 93.1). The case split was 77 COVID-19 cases in the Comirnaty group vs. 833 COVID-19 cases in the placebo group.
    - In addition, VE against severe COVID-19 disease in individuals with or without evidence of prior infection with SARS-CoV-2 was 95.3% (95% CI: 70.9, 99.9). The case split was 1 severe COVID-19 case in the Comirnaty group vs. 21 severe COVID-19 cases in the placebo group.
- Warnings and precautions for Comirnaty include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitation of effectiveness.
    - Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines | CDC).
- The most common adverse reactions (≥ 10%) with Comirnaty use in individuals 16 – 55 years of age were pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, fever, and injection site swelling.
- The most common adverse reactions (≥ 10%) with Comirnaty use in individuals ≥ 56 years of age were pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, and injection site redness.

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- The recommended dosage for Comirnaty is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.
    - There are no data available on the interchangeability of Comirnaty with other COVID-19 vaccines to complete the vaccination series.
    - Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the vaccination series.
    - Refer to the Comirnaty drug label for additional dosing and administration recommendations.

- Pfizer/BioNTech's launch plans for Comirnaty are pending. Comirnaty will be available as a suspension for injection in a carton containing 25 or 195 multiple-dose vials. After dilution, 1 vial contains 6 doses of 0.3 mL.
    - Individuals can receive Pfizer/BioNTech's COVID-19 vaccine authorized under the EUA or Comirnaty.