Spikevax™ (COVID-19 vaccine, mRNA) – New vaccine approval

- On January 31, 2022, the FDA announced the 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.
    - Spikevax and the emergency use authorization (EUA)-authorized Moderna 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 EUA, including for the administration of a third primary series dose in certain immunocompromised individuals who are 18 years of age and older, and as a single booster dose for individuals 18 years of age and older at least five months after completing a primary series of the vaccine. It is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine.

- Spikevax is the second FDA-approved vaccine for the prevention of COVID-19. Comirnaty® (COVID-19 vaccine, mRNA) was approved in August 2021 for the same indication in individuals 16 years of age and older.

- The efficacy of Spikevax was demonstrated in a randomized, placebo-controlled, observer-blinded study enrolling 28,451 participants 18 years of age and older who did not have evidence of prior infection with SARS-CoV-2. Participants were followed for a median length of 4 months after dose 2.
    - There were 55 COVID-19 cases in the Spikevax group vs. 744 cases in the placebo group, with a vaccine efficacy (VE) of 93.2% (95% CI: 91.0, 94.8).
    - In addition, VE against severe COVID-19 disease was 98.2% (95% CI: 92.8, 99.6). There were 2 cases of severe COVID-19 in the Spikevax group vs. 106 cases in the placebo group.
    - The data used for the analyses were accrued before the Omicron variant emerged.

- Warnings and precautions for Spikevax include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine 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 18 through 24 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.

- The most common adverse reactions (≥ 10%) with Spikevax use in individuals 18 to 64 years of age were pain at injection site, fatigue, headache, myalgia, chills, arthralgia, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.

- The most common adverse reactions (≥ 10%) with Spikevax use in individuals ≥ 65 years of age were pain at injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, swelling at the injection site, and axillary swelling/tenderness.

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- The recommended dosage for Spikevax is administered intramuscularly as a series of 2 doses (0.5 mL each) 1 month apart.
    - There are no data available on the interchangeability of Spikevax with other COVID-19 vaccines to complete the vaccination series.
    - Individuals who have received one dose of Spikevax should receive a second dose of Spikevax to complete the vaccination series.
    - Refer to the Spikevax drug label for additional dosing and administration recommendations.
- Moderna's launch plans for Spikevax are pending. Spikevax will be available as a suspension for injection in a carton containing 10 multiple-dose vials of 5.5 mL or 7.5 mL.
    - Individuals can receive Moderna's COVID-19 vaccine authorized under the EUA or Spikevax.