Moderna COVID-19 vaccine – EUA granted for 6 months to 17 years

- On June 17, 2022, the FDA announced the emergency use authorization (EUA) of the Moderna COVID-19 vaccine for the prevention of COVID-19 to include use in children down to 6 months of age.
    - The FDA amended the EUA to include use of the vaccine in individuals 6 months through 17 years of age. The vaccine had previously been authorized for use in adults 18 years of age and older.
    - The FDA authorized for 6 months to 5 years of age, a primary series of two doses (0.25 mL each/25 mcg) 1 month apart. A third primary series dose (0.25 mL/25 mcg) is authorized for administration at least 1 month following the second dose to individuals 6 months through 5 years of age with certain kinds of immunocompromise.
    - The FDA authorized for 6 years to 11 years of age, a primary series of two doses (0.5 mL each/50 mcg) 1 month apart. A third primary series dose (0.5 mL/50 mcg) is authorized for administration at least 1 month following the second dose to individuals 6 years through 11 years of age with certain kinds of immunocompromise.
    - The FDA authorized for 12 years to 17 years of age, a primary series of two doses (0.5 mL each/100 mcg) 1 month apart. A third primary series dose (0.5 mL/100 mcg) is authorized for administration at least 1 month following the second dose to individuals 12 years through 17 years of age with certain kinds of immunocompromise.

- The efficacy and safety of Moderna COVID-19 vaccine for individuals 6 months to 17 years of age was established in two ongoing, randomized, blinded, placebo-controlled clinical studies in the U.S. and Canada.
    - For 6 months to 23 months of age, 230 children received a 2-dose primary series at 25 mcg. Immune response was comparable to immune response seen with a higher dosage in 290 adults 18 – 25 years of age. When the omicron variant was predominant, vaccine efficacy was 50.6%.
    - For 2 to 5 years of age, 260 children received a 2-dose primary series at 25 mcg. Immune response was comparable to immune response seen with a higher dosage in 290 adults 18 – 25 years of age. When the omicron variant was predominant, vaccine efficacy was 36.8%.
    - For 6 to 11 years of age, 320 children received a 2-dose primary series at 50 mcg. Immune response was comparable to immune response seen with a higher dosage in 295 adults 18 – 25 years of age. Vaccine efficacy could not be determined due to low numbers of COVID-19 cases.
    - For 12 to 17 years of age, 340 adolescents received a 2-dose primary series at 100 mcg. Immune response was comparable to immune response seen with an equivalent dosage in 296 adults 18 – 25 years of age. Among approximately 3,000 adolescents, vaccine efficacy was 93.3% prior to the omicron variant becoming predominant.

- Warnings and precautions for Moderna COVID-19 vaccine include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.
    - The FDA and the Centers for Disease Control and Prevention (CDC) analyzed international safety surveillance data to assess the risk of myocarditis, a known adverse event observed with COVID-19 vaccines as well as COVID-19 infection.

Continued . . .

    - Most cases of myocarditis associated with the Moderna vaccine are characterized by rapid resolution of symptoms following conservative management, with no impact on quality of life reported by most patients

- The most common adverse reactions with Moderna COVID-19 vaccine use in children 6 months to 5 years were pain, redness and swelling at the injection site, fever and underarm (or groin) swelling/tenderness of lymph nodes in the same arm (or thigh) as the injection.

- The most common adverse reactions with Moderna COVID-19 vaccine use in both the 6 through 11 age group and the 12 through 17 age group were pain, redness and swelling at the injection site, tiredness, headache, muscle pain, chills, joint pain, underarm swollen lymph nodes in the same arm as the injection, nausea and vomiting and fever.

- The recommended dose of Moderna COVID-19 vaccine in children 6 months to 17 years is given intramuscularly. Refer to individual Moderna COVID-19 vaccine Fact Sheets for additional administration guidelines.

- The Moderna COVID-19 vaccine for children 6 months to 17 years of age will be distributed by the federal government.

    - New Vial Presentation Available: The Moderna COVID-19 vaccine for children 6 months to 5 years of age will be available as multiple-dose vials with dark blue caps and labels with a magenta border containing a volume of 2.5 mL (NDC 80777-279-99). This presentation will begin shipping next week.
    - The Moderna COVID-19 vaccine for children 6 years to 11 years of age is currently available as multiple-dose vials with a dark blue cap and a label with a purple border containing a volume of 2.5 mL (it is marked “for booster doses only”, but is also authorized for the primary series for these children) (NDC 80777-275-05).
    - The Moderna COVID-19 vaccine for adolescents 12 to 17 years of age is currently available as multiple-dose vials with red caps and labels with a light blue border containing a volume of 5.5 mL or 7.5 mL (NDCs 80777-273-99 and 80777-273-98).
    - A wall chart of vials is available here.

What’s Next?

- The CDC’s Advisory Committee on Immunization Practices (ACIP) convened June 17 and 18 will meet to make recommendations on appropriate utilization of the Moderna COVID-19 vaccine in children 6 months to 5 years of age.

- The CDC director will need to sign off on ACIP’s recommendations prior to implementation and could come as early as this weekend.

- ACIP will convene an additional meeting to make recommendations for Moderna’s COVID-19 vaccine in children 6 to 17 years of age.

Optum