February 1st, 2022

COM-2022-011

Dear provider of healthcare-related services,

On January 31st, 2022, the U.S. Food and Drug Administration (FDA) announced the full approval of Moderna's COVID-19 vaccine. It will be marketed as Spikevax™. The vaccine is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARDS-CoV-2) in individuals 18 years of age and older. This vaccine meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality required for approval.

The vaccine has been available under emergency use authorization (EUA) for individuals 18 years of age and older since December 18th, 2020. Spikevax™ is administered intramuscularly as a series of two doses (0.5mL each) one month apart. Moderna vaccine is authorized for use to provide:

- As a two-dose primary series for individuals 18 years of age and older
- As a third primary series for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise
- 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 or with another authorized COVID-19 vaccine.

Spikevax™ is also authorized for emergency use with the same recommendations. This vaccine and the EUA-authorized Moderna COVID-19 vaccine have the same formulation and can be used interchangeably.

The FDA's approval is based on the evaluation and analysis of follow-up safety and effectiveness data from the ongoing randomized, placebo-controlled, blinded clinical trial that supported the December 2020 EUA for the Moderna COVID-19 vaccine. The updated analyses to determine effectiveness of Spikevax™ included 14,287 vaccine recipients and 14,164 placebo recipients 18 years of age and older who did not have evidence of SARS-CoV-2 infection prior to receiving the first dose. The data used for the analyses were accrued before the Omicron variant emerged. The

data demonstrated that Spikevax™ was 93% effective in preventing COVID-19, with 55 cases of COVID-19 occurring in the vaccine group and 744 COVID-19 cases in the placebo group. The vaccine was also 98% effective in preventing severe disease.

The most commonly reported side effects by clinical trial participants were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, nausea/vomiting, swollen lymph nodes under the arm and fever. The label for Spikevax™ includes a warning about the risks of myocarditis and pericarditis and the FDA is requiring Moderna to conduct postmarketing studies to further assess these risks in individuals following vaccination.

The following resources provide detailed information about this approval:

1. FDA News Release: Coronavirus (COVID-19) Update: FDA takes key action by approving second COVID-19 vaccine
2. Spikevax™ package insert
3. Spikevax™ approval letter
4. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine
5. Preliminary report: mRNA vaccine against SARS-CoV-2

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most updated information.

PharmPix is committed to the health and wellness of our members, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 220.

Kind regards,

Clinical Department