

March 1, 2021

**COM-2021-013**

Dear provider of healthcare-related services,

On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the third vaccine for the prevention of 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 EUA allows the Janssen COVID-19 Vaccine to be distributed in the United States (U.S.).

The use of the Janssen COVID-19 Vaccine under this EUA is limited to **all** of the following requirements:

1. The vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider must communicate to the individual receiving the vaccine or their caregiver information consistent with the "[Fact Sheet for Recipients and Caregivers](#)" prior to receiving the vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or another designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors, whether or not associated with an adverse event,
  - serious adverse events (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
  - cases of COVID-19 that result in hospitalization or death.
5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the vaccine to recipients.

Please refer to the following sources for additional important details:

1. "[Letter of authorization](#)" – Includes details regarding the scope of authorization, product description, the specific conditions that must be met, among other important information.
2. "[Fact Sheet for Healthcare Providers Administering Vaccine](#)" – Contains instructions for healthcare providers, dosage and administration details, contraindications, warnings, reported adverse reactions, information to provide to vaccine recipients/caregiver, mandatory requirements

for the vaccine administration under EUA, how to report adverse events, information regarding the authority for issuance of the EUA, and the full EUA prescribing information.

3. "[COVID-19 Vaccination Program Operational Guidance](#)" – Serves as an interim playbook for state, territorial, tribal, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions.

Additional information can be found at the [FDA's COVID-19 Vaccines portal](#) and the Centers for Disease and Control Prevention (CDC) website.

The situation with the COVID-19 pandemic is dynamic and continuously changing. We strongly encourage the frequent revision of updated information provided by the FDA and the CDC to assure that your practices are consistent with the most actualized information.

PharmPix is committed to our members' health and wellness. It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

Clinical Department

References:

1. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. (2021). Retrieved March 2021, from <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.
2. COVID-19 Vaccines. U.S. Food and Drug Administration. Retrieved March 2021, from <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#news>.
3. COVID-19 Vaccination Program Operational Guidance. Cdc.gov. Retrieved March 2021, from <https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html>.