

Issue Brief

Janssen Biotech, Inc. COVID-19 Vaccine Emergency Use Authorization Vaccination Implementation Resources

March 2021

The FDA issuance of an Emergency Use Authorization (EUA) of the Janssen Biotech, Inc. vaccine to prevent COVID-19 illness marks a major milestone toward fighting the pandemic. This document provides a summary of key information and resources to assist state and territorial health departments with implementation of the first phase of COVID-19 vaccination. A timeline of events leading to the FDA EUA and the Advisory Committee on Immunization Practices (ACIP) use recommendations and list of key resources are below:

Timeline

- **Feb. 4:** Janssen Biotech, Inc. [submitted](#) an EUA request for the vaccine, Ad26.COV2.S, to prevent COVID-19 caused by SARS-CoV-2.
- **Feb. 26:** The [Vaccines and Related Biological Products Advisory Committee](#) met to discuss the EUA request for a COVID-19 vaccine from Janssen, which is proposed for use in individuals 18 years of age and older. The committee received a [briefing document](#) and addendum to aid discussions related to the vaccine.
- **Feb. 26:** FDA [authorized](#) the Janssen COVID-19 vaccine for use among persons 18 years and older.
- **Feb. 28:** [ACIP](#) voted 12 to 0, with one recusal, to issue an interim recommendation for use of the Janssen COVID-19 vaccine in persons 18 years and older under the FDA emergency authorization. Rochelle Walensky, director of CDC, approved the recommendations and CDC published an MMWR on March 2. The [MMWR](#) includes specific research, including a detailed summary of [safety data](#), a [GRADE review](#) of the evidence for benefits and harms, and information on [administration](#) and use in special populations.

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Factsheets were developed by Janssen Biotech, Inc. to distribute to healthcare providers administering the vaccine, as well as to their patients.

- [Factsheet for Healthcare Providers Administering Vaccine](#)
- [Factsheet for Recipients and Caregivers](#)

CDC Materials to Support Implementation

A variety of materials have been released to train and assist healthcare providers with vaccine administration.

- [COVID-19 Vaccine Storage and Handling, ACIP Recommendations, and EUA](#)
- [COVID-19 Vaccine Product Information](#)
- [Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents](#) (Last updated Dec. 3)
- [CDC's COVID-19 Vaccination Communication Toolkit for Medical Centers, Clinics, and Clinicians](#)
- [Training and Education Materials](#) and [Quick Link](#) (Healthcare Provider Training Modules)

- [V-Safe information](#) (New CDC Text/Web Based Adverse Event System)

Cold Chain, Storage, and Dry Ice Operations

The Cybersecurity & Infrastructure Security Agency has developed [critical questions and considerations](#) that may inform and assist in further reducing risk to these life-saving efforts.

Additional Information

CDC is offering direct technical assistance and support through these mechanisms:

- CDC's Vaccine Coordination Center launched a 24/7 Jurisdictional Watch Desk to provide COVID-19 vaccine technical assistance to the 64 jurisdictions funded by the Immunization Services Division. The Jurisdictional Watch Desk began operations at 8 a.m. ET Friday, Dec. 11, and will operate 24 hours a day, seven days a week. (Local health departments will be directed to their state or territorial health department.)
- The CDC Clinician On-Call Center launched a 24-hour hotline with trained CDC clinicians standing by to answer COVID-19 questions from healthcare personnel on a wide range of topics, such as diagnostic challenges, clinical management, and infection prevention and control. To reach this service, call 800-CDC-INFO (800-232-4636) and ask for the Clinician On-Call Center.
- CDC field staff are being assigned to immunization and preparedness programs and will be visiting a sample of sites to observe and document receipt of vaccine shipment and integrity. These visits will be communicated with jurisdictions beforehand and support process improvements as needed. The field staff will complete the brief online survey on behalf of the sites they are observing and send photos to CDC documenting any concerning aspects of the shipment.