

Moderna COVID-19 Vaccine Emergency Use Authorization Resources

Dec. 22, 2020

FDA's [issuance](#) of an Emergency Use Authorization (EUA) of the Moderna vaccine to prevent COVID-19 illness marks another 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 phases of COVID-19 vaccination. A timeline of events leading to the FDA EUA, resources on the Advisory Committee on Immunization Practices (ACIP) use recommendations, and a list of key resources are below.

Timeline

- **Dec. 17:** The Vaccines and Related Biological Products Advisory Committee recommended—in a unanimous vote, with one abstention—to endorse the Moderna COVID-19 vaccine for people ages 18 and older based on a favorable benefit-risk profile. The committee received a [briefing document](#) to support [discussions](#) related to the vaccine. Discussions were focused on rare potential side effects and anaphylaxis. While Moderna noted that anaphylaxis was not seen during the clinical trials, they will continue to monitor this and other adverse events long term.
- **Dec. 18:** FDA [authorized](#) the Moderna COVID-19 vaccine for use among persons 18 years of age and older. The decision culminated through a [documented](#) review process.
- **Dec. 19:** ACIP voted 11 to 0, with three recusals due to conflicts, to issue an interim recommendation for use of the Moderna COVID-19 vaccine in persons older than 18 years under the FDA emergency use authorization. Robert Redfield, director of CDC, approved the recommendations, and CDC published [MMWR: ACIP Interim Recommendation for Use of Moderna COVID-19 Vaccine \(Dec. 20\)](#). 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](#).

CDC Materials to Support Implementation

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

General Resources

- [CDC's COVID-19 Vaccination Communication Toolkit for Medical Centers, Clinics, and Clinicians](#).
- [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized for Use in the U.S.](#) (last updated Dec. 20).
- [Interim Considerations: Preparing for the Potential Management of Anaphylaxis at Vaccination Sites](#) (last updated Dec. 16).
- [Product Information by Vaccine](#) (storage and handling, ACIP recommendations, and EUA).
- [V-Safe information](#) and [VAERS](#) (adverse event systems).

CDC-Produced Moderna Resources

- [Adverse Events and Reactions](#) (clinical trial results from the Moderna vaccine).
- [Moderna Vaccine Questions](#) (FAQs about vaccine supply, distribution, and administration).

- [Moderna COVID-19 Vaccine Standing Orders.](#)
- [Preparation and Administration Summary.](#)
- [Vaccine Expiration Date Tracking Tool.](#)

Moderna COVID-19 Vaccine Emergency Use Authorization Materials

Factsheets were developed by Moderna to hand out to healthcare providers administering the vaccine and their patients. In addition, Moderna developed resources on their website for both providers and vaccine recipients.

- [Factsheet for Healthcare Providers.](#)
- [Factsheet for Patients.](#)
- [Provider Information](#) (storage and handling, dosing and administration, FAQ, who is eligible for the vaccine, and clinical trial data).
- [Vaccine Recipient Information](#) (FAQ and who is getting vaccinated).
- [Vaccine Expiration Date Lookup](#) (Moderna).

Cold Chain, Storage, and Dry Ice Operations

The Cybersecurity and Infrastructure Security Agency 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.