



Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak

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What You Need to Know

- The [U.S. national monkeypox vaccine strategy](#) was announced on June 28, 2022. Multiple federal agencies, including the [Administration for Strategic Preparedness and Response \(ASPR\)](#), [U.S. Food and Drug Administration \(FDA\)](#), [National Institutes of Health \(NIH\)](#), and [Centers for Disease Control and Prevention \(CDC\)](#) are coordinating to implement this enhanced vaccination strategy.
- This document provides interim guidance regarding use of JYNNEOS and ACAM2000 vaccines during the monkeypox outbreak that began in the United States on May 17, 2022. This interim guidance is in addition to standard guidance and recommendations for use of these vaccines from CDC's [Advisory Committee on Immunization Practices \(ACIP\)](#).
- Two vaccines may be used for the prevention of monkeypox disease:
 - JYNNEOS vaccine is approved for the prevention of monkeypox and smallpox disease.
 - ACAM2000 vaccine is approved for immunization against smallpox disease and made available for use against monkeypox under an Expanded Access Investigational New Drug (EA-IND) protocol.
- The standard regimen for JYNNEOS involves a subcutaneous (Subcut) route of administration with an injection volume of 0.5mL. In the context of the current national [Public Health Emergency \(PHE\)](#), an alternative regimen involving intradermal (ID) administration with an injection volume of 0.1mL may be used under an Emergency Use Authorization (EUA).
- People can be vaccinated after exposure to monkeypox virus to help prevent monkeypox disease (i.e., post-exposure prophylaxis).
- No data are currently available on the clinical efficacy or effectiveness of JYNNEOS or ACAM2000 vaccines in the current outbreak.

- Because there are limitations in our knowledge about the effectiveness of these vaccines in the current outbreak, people who are vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.
- Globally and in the United States, supply of JYNNEOS vaccine is currently limited, although more is expected in the coming weeks and months. In the United States, there is a large supply of ACAM2000, but this vaccine has more side effects and contraindications.

Purpose and Scope

- This document provides interim guidance for healthcare professionals and public health officials regarding use of JYNNEOS and ACAM2000 vaccines during the monkeypox outbreak that began in the United States on May 17, 2022. Considerations apply only to the use of vaccine products in the United States. This interim guidance is in addition to existing standard guidance and recommendations for use of these vaccines from CDC's [Advisory Committee on Immunization Practices \(ACIP\)](#). Considerations presented in this document are [interim guidelines](#), which are developed in response to emergencies, such as outbreaks and natural or manmade disasters. The term interim implies that CDC developed these guidelines using either expert opinion, indirect evidence, or emerging evidence, and these recommendations might change when additional evidence becomes available. This document is informed by data and considerations from U.S. federal agencies including ASPR, FDA, NIH, and CDC, [general best practice guidelines for immunization](#), other data sources, and expert opinion.

Related Resources

[JYNNEOS Package Insert](#)

[Video: Administering JYNNEOS Intradermally](#)

[JYNNEOS Vaccine Information Statement \(VIS\) \[151 KB, 2 pages\]](#)

[Images: Administering JYNNEOS Intradermally \[ZIP – 29 MB\]](#)

[JYNNEOS Vaccine Information Statement \(VIS\) in Spanish \[165 KB, 2 pages\]](#)

[ACAM 2000 Medication Guide](#)

[JYNNEOS Storage and Handling Summary \[1.1 MB, 2 pages\]](#)

[Vaccination Operational Planning Guide](#)

[JYNNEOS Standing Orders \(Standard Regimen\) \[233 KB, 3 pages\]](#)

[FDA EUA Fact Sheet for Providers \[900 KB, 16 pages\]](#)

[JYNNEOS Standing Orders \(Alternative Regimen\) \[243 KB, 3 pages\]](#)

[FDA EUA Fact Sheet for Patients and Caregivers \[465 KB, 5 pages\]](#)

[JYNNEOS Preparation and Administration Summary \(Standard Regimen\) \[240 KB, 2 pages\]](#)

[FDA EUA Fact Sheet for Patients and Caregivers in Spanish \[228 KB, 5 pages\]](#)

[JYNNEOS Preparation and Administration Summary \(Alternative Regimen\) \[249 KB, 2 pages\]](#)

[FDA EUA Fact Sheet for Patients and Caregivers in Other Languages](#)

[Monkeypox Vaccination Program Provider Agreement](#)