Centers for Disease Control and Prevention

Vaccination Strategies

Updated August 9, 2022

Vaccines

Two vaccines may be used for the prevention of monkeypox disease:

- JYNNEOS vaccine is used for the prevention of smallpox and monkeypox disease among people determined to be at high risk for infection.
- ACAM2000 vaccine is approved for immunization against smallpox disease for people determined to be at high risk for infection. It has been made available for use against monkeypox in the current outbreak.

JYNNEOS is a third-generation vaccine based on a live, attenuated non-replicating orthopoxvirus, Modified Vaccinia Ankara (MVA). MVA is a live virus that does not replicate efficiently in humans. JYNNEOS is known internationally as Imvamune or Imvanex, and is manufactured by Bavarian Nordic.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of JYNNEOS for:

- Active immunization by intradermal injection for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection.
- Active immunization by subcutaneous injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox infection.

ACAM2000 is a second-generation vaccine indicated for the prevention of smallpox disease. It has been made available for use against monkeypox in the current outbreak under an Expanded Access Investigational New Drug (EA-IND) protocol, which requires informed consent along with completing additional forms. ACAM2000 contains a live vaccinia virus that is replication-competent in humans. ACAM2000 is manufactured by Emergent BioSolutions.

Available evidence supporting the use of smallpox vaccine for monkeypox prevention is derived from the vaccine used during smallpox eradication, Dryvax. Dryvax was a first-generation smallpox vaccine manufactured by Wyeth laboratories that is no longer available. Routine use of this vaccine was stopped in 1972 after smallpox was eradicated from the United States. The license was withdrawn in 2008 and no supplies of this vaccine remain.

Globally and in the United States, supply of JYNNEOS vaccine is currently limited, although more is expected in the coming weeks and months. The United States has a large supply of ACAM2000, but this vaccine has more side effects and contraindications than JYNNEOS.

In the context of limited vaccine supply, JYNNEOS vaccine doses should be prioritized for people who are at high risk for severe disease caused by infection with the *Monkeypox virus* (including, but not limited to, people with HIV infection or other immunocompromising conditions, who are pregnant, or who are at increased risk for serious adverse events following ACAM2000 vaccination).

ACAM2000 vaccination).

Vaccination Strategies

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.

People can be vaccinated after known or presumed exposure to someone with monkeypox [i.e., post-exposure prophylaxis (PEP)], ideally within 4 days. Additionally, people with certain risk factors and recent experiences that might make them more likely to have been recently exposed to monkeypox can be considered for vaccination [i.e., expanded post-exposure prophylaxis (PEP++)]. Jurisdictional vaccine strategies should reflect national priorities to primarily employ PEP and PEP++ approaches, and should prioritize PEP first, before other vaccination strategies. When combined with other prevention measures including self-isolation, PEP and PEP++ might help control outbreaks by reducing transmission of *Monkeypox virus*, preventing disease, or reducing severity of disease.

Currently, CDC is not encouraging mass vaccination for the general public or for all sexually active people. While JYNNEOS vaccine supplies remain limited, widespread implementation of pre-exposure prophylaxis (PrEP) is not feasible. However, in some jurisdictions, consideration of monkeypox vaccine PrEP for individuals at increased risk of monkeypox from non-occupational exposure might start to be considered. Where applicable, plans to introduce PrEP should focus on strategies likely to have the largest impact in slowing the current outbreak. To be most effective, monkeypox vaccine PrEP strategies should be part of a larger prevention effort. Such an effort should include health equity principles as a foundation and include strategies such as community outreach, education efforts, and communication about behavioral strategies to minimize risk. PrEP strategies are likely to be most effective when designed and implemented in partnership with communities and groups that are disproportionately affected. For example, successful HIV PrEP campaigns were built on a high level of community engagement and have built a high amount of trust. Jurisdictions wishing to use JYNNEOS for PrEP should develop strategies to ensure fair and equitable availability of vaccines. In addition, jurisdictions should hold some vaccine in reserve to account for PEP and expanded PEP needs in the coming months, until more vaccines are made available. As more vaccine becomes available, interim guidance on the introduction of PrEP strategies may be updated.

ACIP recommendations that predate this outbreak are unchanged to use JYNNEOS or ACAM2000 as PrEP specifically for people in certain occupational risk groups.

Table 1. Vaccination Strategies Used in the 2022 U.S. Monkeypox Outbreak

Strategy	Definition	Criteria
Post-Exposure Prophylaxis (PEP)	Vaccination **after known exposure** to monkeypox	• People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment
Expanded Post-Exposure Prophylaxis (PEP++)	Vaccination **after known or presumed** exposure to monkeypox	Any of the following: • People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment • People who are aware that a recent sex partner within the past 14 days was diagnosed with monkeypox • Certain gay, bisexual, or other men who have sex with men, or transgender people, who have had any of the following within the past 14 days: sex with multiple partners (or group sex); sex at a commercial sex venue; or sex in association with an event, venue, or defined geographic area where monkeypox transmission is occurring

		area where monkeypox transmission is occurring
Pre-Exposure Prophylaxis (PrEP)	Vaccination **before exposure** to monkeypox	• People in certain occupational risk groups*

*People at risk for occupational exposure to orthopoxviruses include research laboratory workers performing diagnostic testing for *Monkeypox virus,* and members of health care worker response teams designated by appropriate public health and antiterror authorities (see ACIP recommendations).

Timing of post-exposure prophylaxis

CDC recommends initiating vaccination within 4 days following the date of exposure for the best chance to prevent onset of the disease.

If initiated between 4 and 14 days following the date of exposure, vaccination might be less effective. Benefits might still outweigh risks when administering vaccine more than 14 days after exposure in some clinical situations (e.g., for a severely immunosuppressed person with a recent sex partner confirmed to have monkeypox).

Vaccination given after the onset of signs or symptoms of monkeypox is not expected to provide benefit.

Planning Considerations for Health Departments and Providers

Vaccine Access Considerations

- Both vaccines are available from the Strategic National Stockpile (SNS) by jurisdiction request.
- Potential adult or pediatric use of ACAM2000 and potential pediatric use of JYNNEOS should be considered in consultation with CDC.
- Either JYNNEOS or ACAM2000 can be used in accordance with the national vaccination strategy (e.g., for PEP, PEP++, or PrEP), following risk-benefit discussions and a review of any conditions that could increase risk for serious adverse events.
- When developing vaccine distribution plans, jurisdictions should consider the current epidemiology of the outbreak as well as health equity considerations.

Health Equity Considerations

- Engage people from affected communities in planning for vaccine programs and as trusted sources of information about both monkeypox disease and vaccination
- Use non-stigmatizing, plain language
- Reiterate privacy of information and how data will be used
- Engage diverse partners already working with special populations
- Bring vaccines to where people are through pop-up events and mobile outreach
- To improve accessibility, offer multiple opportunities and times to be vaccinated, including evenings and weekends
- Leverage clinical venues that serve people who have historically had less access to primary care, including sexual health clinics, transgender health clinics, and pharmacies
- Use multiple channels, such as, social media, websites, or flyers to advertise and book appointments
- Minimize the use of systems that are first-come, first-served; equity interventions that prioritize populations less able to access vaccine should be implemented even if a first-come, first-served model is used

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Related Resources

- JYNNEOS Package Insert
- JYNNEOS Vaccine Information Statement (VIS) [151 KB, 2 pages]
- JYNNEOS Storage and Handling Summary [1.1 MB, 2 pages]
- ACAM 2000 Medication Guide
- Vaccination Operational Planning Guide
- FDA EUA Fact Sheet for Providers [900 KB, 16 pages]
- FDA EUA Fact Sheet for Patients and Caregivers [465 KB, 5 pages]

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