

# **Monkeypox Outbreak—United States, 2022:**

Situational Update, ACIP Recommendations for Occupational Pre-Exposure Prophylaxis, and Monkeypox Outbreak Response National Vaccine Strategy

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**Situational Update**

# Monkeypox

- Rare, sometimes life-threatening zoonotic infection
- Endemic in west and central Africa
- Caused by monkeypox virus (an orthopoxvirus)
- Specific animal reservoir unknown, but likely small rodents (rope squirrel, Gambian rat, dormouse)
- Can spread from infected animals to humans and person-to-person
  - Respiratory secretions
  - Skin-to-skin contact with infected body fluids (e.g., fluid from vesicles and pustules)
  - Fomites (e.g., shared towels, contaminated bedding)
- **Clinical presentation:** disseminated vesicular/pustular rash associated with fever, lymphadenopathy, malaise

## Examples of Monkeypox Rashes

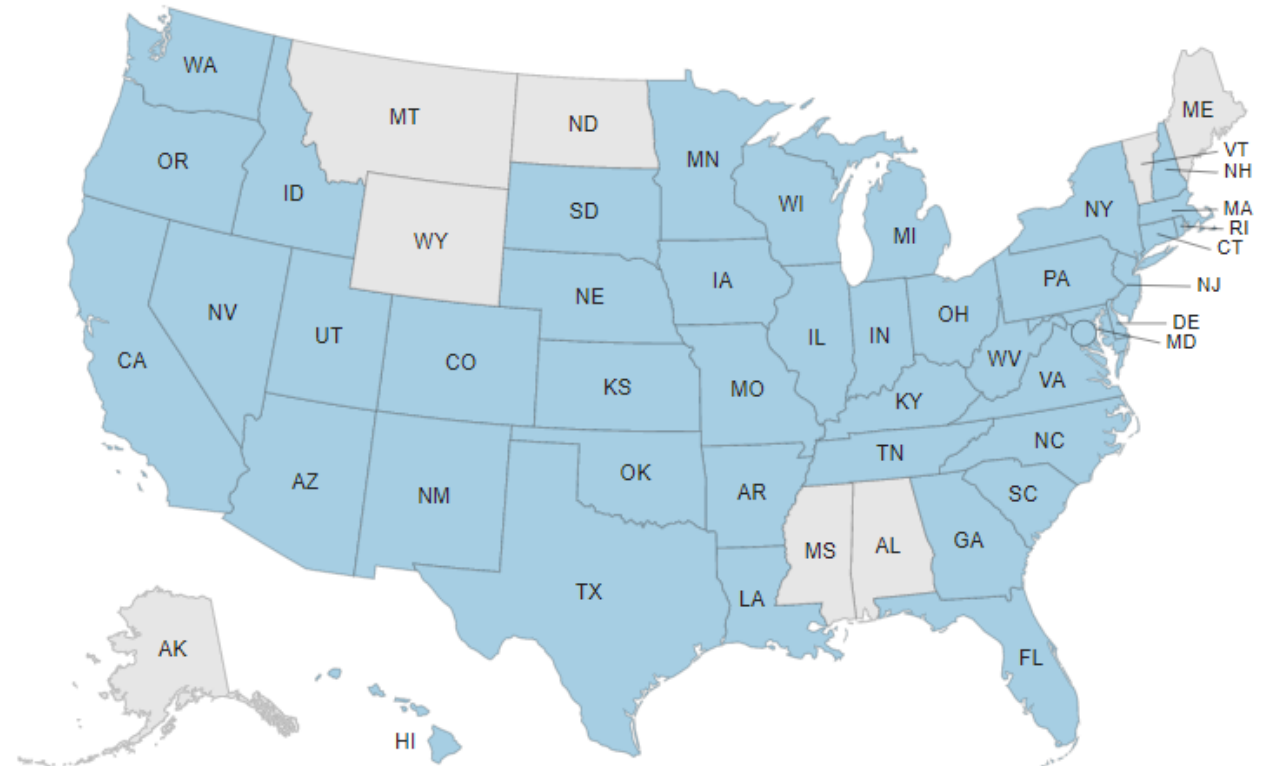
Photo Credit: NHS England High Consequence Infectious Diseases Network



# Outbreak Summary

## U.S. Map & Case Count (July 14, 2022)

- As of July 14, 2022:
  - 1,470 confirmed monkeypox/orthopoxvirus cases in the United States
  - 11,466 confirmed monkeypox/orthopoxvirus cases in countries, territories, areas that have not historically reported monkeypox worldwide
- Most (but not all) cases are among gay, bisexual, or other men who have sex with men



Territories PR



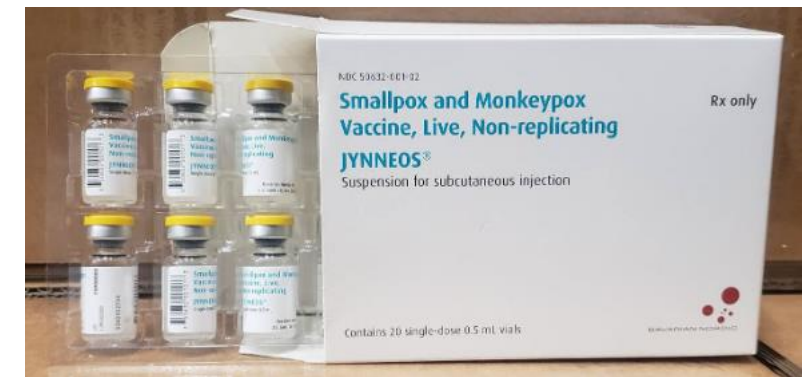
For the latest case counts, visit:

<https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html>

**Vaccines Stockpiled for Orthopoxviruses**

# JYNNEOS

- Live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus
  - Also known as IMVAMUNE, IMVANEX, MVA
- Licensed by FDA in September 2019
  - 2-dose series (subcutaneous injections, 28 days apart)
  - Indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection
- CDC is developing an Expanded Access Investigational New Drug (EA-IND) protocol to allow the use of JYNNEOS for monkeypox in pediatric populations

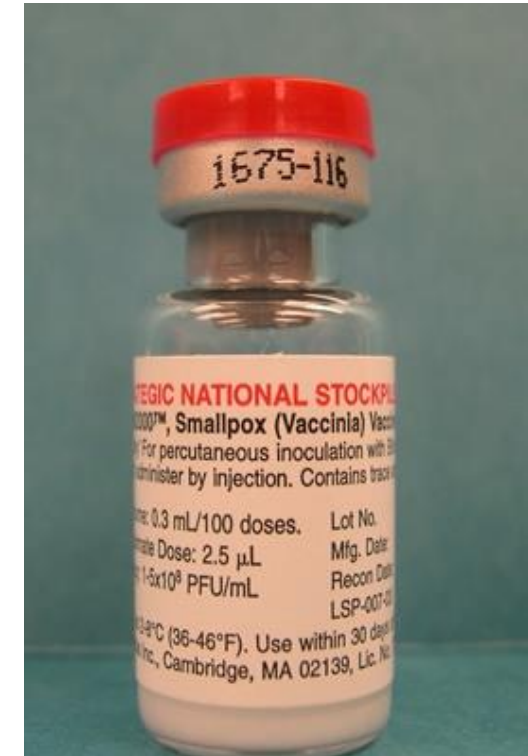


# ACAM2000

- Live vaccinia virus vaccine
- Licensed by FDA in August 2007
  - Administered as 1 percutaneous dose via multiple puncture technique with a bifurcated needle
  - Indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection
- **Replaced Dryvax** - license withdrawn by manufacturer and remaining vaccine destroyed
- **CDC-held EA-IND protocol allows use for Non-Variola Orthopoxvirus Infection (e.g., monkeypox) during an outbreak**

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a6.htm>

<https://www.fda.gov/media/75792/download>



# ACAM2000 and JYNNEOS

|                                                    | ACAM2000                                                                   | JYNNEOS                                                                     |
|----------------------------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>Vaccine virus</b>                               | Replication-competent vaccinia virus                                       | Replication-deficient modified vaccinia Ankara                              |
| <b>“Take”</b>                                      | “Take” occurs                                                              | No “take” after vaccination                                                 |
| <b>Inadvertent inoculation and autoinoculation</b> | Risk exists                                                                | No risk                                                                     |
| <b>Serious adverse event</b>                       | Risk exists                                                                | Fewer expected                                                              |
| <b>Cardiac adverse events</b>                      | Myopericarditis in 5.7 per 1,000 primary vaccinees                         | Risk believed to be lower than that for ACAM2000                            |
| <b>Effectiveness</b>                               | FDA assessed by comparing immunologic response and “take” rates to Dryvax* | FDA assessed by comparing immunologic response to ACAM2000 & animal studies |
| <b>Administration</b>                              | Percutaneously by multiple puncture technique in single dose               | Subcutaneously in 2 doses, 28 days apart                                    |

\*Both ACAM2000 and Dryvax are derived from the NYC Board of Health strain of vaccinia; ACAM2000 is a “second generation” smallpox vaccine derived from a clone of Dryvax, purified, and produced using modern cell culture technology.

# **ACIP Recommendations for Occupational Pre-Exposure Prophylaxis (PrEP)**

# ACIP Recommendations for Occupational PrEP

- On November 3, 2021, the Advisory Committee on Immunization Practices (ACIP) voted to recommend vaccination for select persons at risk for occupational exposure to orthopoxviruses
- Policy note published June 3, 2022
  - Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 (Rao et al., 2022)

<http://dx.doi.org/10.15585/mmwr.mm7122e1>

# Pre-Exposure Prophylaxis

- **People who should get PrEP**
  - **Clinical laboratory personnel who perform testing to diagnose orthopoxviruses**, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including Monkeypox virus
  - **Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans**, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains
  - **Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes**

# Pre-Exposure Prophylaxis, cont.

- **People who may get PrEP**
  - Health care personnel who administer ACAM2000
  - Health care personnel who care for patients infected with orthopoxviruses
- **At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP**
  - Laboratorians should consult with laboratory biosafety officers and supervisors to identify risks and precautions, depending on the type of work they are doing
  - Clinicians and laboratorians should use recommended infection control practices
- **Current ACIP recommendations do not address PrEP for the general population or post-exposure prophylaxis (PEP)**

# Contraindications for ACAM2000 and JYNNEOS for PrEP

| Contraindication                                                                 | ACAM2000<br>Primary<br>Vaccinees | ACAM2000<br>Revaccinees | ACAM2000<br>Household<br>Contacts* | JYNNEOS |
|----------------------------------------------------------------------------------|----------------------------------|-------------------------|------------------------------------|---------|
| History or presence of atopic dermatitis                                         | X                                | X                       | X                                  |         |
| Other active exfoliative skin conditions                                         | X                                | X                       | X                                  |         |
| Conditions associated with immunosuppression                                     | X                                | X                       | X                                  |         |
| Pregnancy                                                                        | X                                | X                       | X                                  |         |
| Aged <1 year                                                                     | X                                | X                       | X                                  |         |
| Breastfeeding                                                                    | X                                | X                       |                                    |         |
| Serious vaccine component allergy                                                | X                                | X                       |                                    | X       |
| Known underlying heart disease (e.g., coronary artery disease or cardiomyopathy) | X                                | X                       |                                    |         |
| Three or more known major cardiac risk factors                                   | X                                |                         |                                    |         |

\*Household contacts include persons with prolonged intimate contact with the potential vaccinee (e.g., sexual contacts) and others who might have direct contact with the vaccination site or with potentially contaminated materials (e.g., dressings or clothing). JYNNEOS is a replication-deficient vaccine and therefore should not present a risk of transmission to household contacts.

# **Monkeypox Outbreak Response**

## **National Vaccine Strategy**

# Monkeypox Outbreak Response in the US

- **Surveillance** (case identification, laboratory confirmation)
- **Containment** (isolation of cases, contact tracing)
- **Vaccination of close contacts (PEP) based on risk exposure assessment\***
- **Vaccine strategy considerations as the outbreak evolved**
  - Jurisdictions with larger numbers of cases are reporting that high percentages of contacts cannot be identified
  - Currently limited supply of JYNNEOS
  - Some jurisdictions have expressed concerns about potential serious adverse events with use of ACAM2000

\*<https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure>

<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>

# Current National Vaccine Strategy

- **Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)**
  - For the current outbreak, this approach can be considered as “standard PEP” for monkeypox
  - People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus
    - **High degree of exposure:** PEP recommended
    - **Intermediate degree of exposure:** Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks
    - Brief interactions and those conducted using appropriate PPE in accordance with Standard Precautions are not high risk and generally do not warrant PEP

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#exposure>

<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>

# Considerations for PEP

- CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease
- If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease
- However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox

# Current National Vaccine Strategy, cont.

- **Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++**
  - For the current outbreak, this expanded approach can be considered as “individual-directed PEP” for monkeypox
  - Public health officials refer to it as “expanded PEP” or “PEP++”
  - People with certain risk factors are more likely to have been recently exposed to monkeypox; the PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox
- **Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP):** This approach refers to administering vaccine to someone at high risk for monkeypox (for example laboratory workers who handle specimens that might contain monkeypox virus)

# JYNNEOS Allocations

- **Given the currently limited supply, JYNNEOS vaccine is being allocated to jurisdictions for use for the following individuals:**
  - Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
  - Presumed contacts who may meet the following criteria:
    - Know that a sexual partner in the past 14 days was diagnosed with monkeypox
    - Had multiple sexual partners in the past 14 days in a jurisdiction with known monkeypox
- **JYNNEOS doses should be prioritized for those people who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions)**

# Vaccine Supply

## ■ JYNNEOS

- 56,000 doses in Phase 1 (June 28, 2022)
- 240,000 doses in the coming weeks
  - Phase 2a (July 8, 2022): 144,000 doses
- >750,000 doses to be made available over the summer
- 500,000 doses will undergo completion, inspection, and release throughout the fall
- HHS anticipates making ~1.9 million doses available in 2022, with an additional 2.2 available during the first half of 2023

## ■ ACAM2000

- >100 million doses

<https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/28/fact-sheet-biden-harris-administrations-monkeypox-outbreak-response/>;  
<https://www.hhs.gov/about/news/2022/07/07/biden-harris-administration-make-additional-144000-doses-jynneos-vaccine-available-states-jurisdictions-for-monkeypox-response.html>;  
<https://aspr.hhs.gov/ASPRBlog/Pages/BlogDetailView.aspx?ItemID=432>

# Considerations for Monkeypox Vaccination

- No data are available yet on the effectiveness of these vaccines in the current outbreak
- People who get 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
- To better understand the protective benefits of these vaccines in the current outbreak, CDC will collect data on any side effects and whether the way the person was infected makes any difference in how well the vaccine protects them

\*<https://www.cdc.gov/poxvirus/monkeypox/prevention.html>

<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>

# Special Considerations for JYNNEOS

- Two doses of JYNNEOS are required, as this is the FDA-approved dosing regimen
- JYNNEOS has been evaluated in clinical studies involving people with HIV infection and atopic dermatitis and shown to be safe and effective in eliciting an immune response in these populations
- People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose
- We do not know if JYNNEOS will fully protect against monkeypox virus infection in this outbreak
  - Individuals wanting to minimize their risk of infection should take additional preventive measures and self-isolate as soon as they develop monkeypox symptoms, such as a rash
  - Infections despite vaccination may occur, and there are currently no data on effectiveness of JYNNEOS from the current outbreak

# Special Considerations for ACAM2000

- **Adverse events following ACAM2000, including myopericarditis or Vaccinia virus transmission to household contacts, can be serious**
  - ACAM2000 will be made available for individuals who decide in consultation with their healthcare provider that the potential benefits of vaccination outweighs any potential risks from ACAM2000 adverse events
- **Recipients should be informed of the risks and benefits of ACAM2000 prior to vaccination**
  - People who are eligible for and offered ACAM2000 should be tested for HIV to ensure they are HIV negative, counseled on potential side effects, and sign an informed consent
  - Recipients should be advised to keep the vaccination site covered and to avoid swimming, sharing of blankets and towels, and contact with people who might be at risk for serious adverse events, such as people with weakened immune systems, atopic dermatitis/eczema, children younger than 12 months, or people who are pregnant

# Special Considerations for ACAM2000, cont.

- Providers should be properly trained on administration of ACAM2000 using a bifurcated needle and should follow up with the patient to assess the vaccination site for a vaccination “take”\*
  - Any provider can administer ACAM2000
  - Training may be obtained online through a CDC training video
- Providers should advise the vaccine recipient on how to keep the vaccination site clean and covered until the lesion completely heals (up to 6 weeks or more)
- People who receive ACAM2000 are considered to reach maximum immunity ~1 month after their dose
- Since there are currently no data on the effectiveness of ACAM2000 from the current outbreak, people who get this vaccine should continue to take steps to protect themselves from infection even after vaccination takes full effect

\*See Smallpox vaccination and adverse reactions: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm>  
<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>

# Planning Considerations for Health Departments and Providers

- **Access to Vaccine**
  - Both vaccines are available from the Strategic National Stockpile (SNS)
  - Either JYNNEOS or ACAM2000 can be used for PEP, PEP++, or PrEP, following risk-benefit discussions and a review of any conditions that could increase risk for serious adverse events
- **Consider the following approaches to ensure equitable distribution:**
  - Engage diverse partners already working with special populations
  - Use non-stigmatizing language
  - Reiterate privacy of information and how data will be used
  - Bring vaccines to where people are through pop-up events and mobile outreach
  - Engage people with lived experience in planning and through peer education models

# Resources

- **Smallpox vaccination information:** <https://www.cdc.gov/smallpox/clinicians/vaccination.html>
- **JYNNEOS**
  - 2022 ACIP Recommendations: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm>
  - Package insert: <https://www.fda.gov/media/131078/download>
  - VIS (English): <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf>
  - VIS (Spanish): [https://www.immunize.org/vis/pdf/spanish\\_smallpox\\_monkeypox.pdf](https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf)
- **ACAM2000**
  - 2016 ACIP Recommendations: <https://www.cdc.gov/mmwr/volumes/65/wr/mm6510a2.htm>
  - Package insert: <https://www.fda.gov/media/75792/download>
  - Medication guide: <https://www.fda.gov/media/75800/download>
  - CDC videos on administering ACAM2000: <https://www.cdc.gov/smallpox/clinicians/administering-acam2000.html>
  - Smallpox vaccination and adverse reactions, guidance for clinicians: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm>



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