VDH VIRGINIA DEPARTMENT OF HEALTH

Order Authorizing Dispensing and Administering of Monkeypox/Smallpox Vaccine Under Virginia Code 54.1-3408(P)
JYNNEOS | ACAM2000

Date Issued: 11/1/2022

Purpose: To help prevent the spread of monkeypox, which is an infectious viral disease stemming from orthopoxvirus. The risk of death is fairly low; however, monkeypox virus cases may be severe, especially in children, pregnant women, or people with suppressed immune systems. This order is intended to supplement existing authorization under the Public Readiness and Emergency Preparedness (PREP) Act, specifically the Amendment effective September 28, 2022.

This Order Authorizes:

- Pharmacists actively licensed in Virginia, who are in good standing to practice in Virginia per the Virginia Board of Pharmacy, to dispense and administer FDA-authorized or approved monkeypox vaccines in accordance with the CDC/ACIP Monkeypox Vaccine Guidance for patients ages 3 years and older;
- Pharmacy technicians and pharmacy interns, who meet the requirements of the PREP Act acting under the supervision of a pharmacist, as defined above, to administer FDA-authorized or approved monkeypox vaccines in accordance with the CDC/ACIP Monkeypox Vaccine Guidance for patients ages 3 years and older; and
- Registered nurses (RNs) and licensed practical nurses (LPNs) actively licensed in Virginia, who are in good standing to practice in Virginia per the Virginia Board of Nursing, to administer FDA-authorized or approved monkeypox vaccines in a pharmacy or on behalf of the Virginia Department of Health (i.e. contracted vendors), in accordance with the CDC/ACIP Monkeypox Vaccine Guidance.

Eligible providers shall administer monkeypox vaccines in accordance with Virginia Code §54.1-3408 (P) as described below.

This order is effective to the earlier of two (2) years from the date of issuance or the expiration of the U.S. Department of Health and Human Services (HHS) monkeypox public health emergency (PHE) declaration signed by Secretary Xavier Becerra, unless otherwise discontinued by the Commissioner or upon his resignation, removal, or retirement.

The vaccinating provider must attest to adhere to the requirements set forth in the **HHS provider agreement**; this includes all policies and procedures included in the agreement, including ensuring proper vaccine storage and handling and documentation. In addition, the site must adhere to all CDC/ACIP-recommended guidelines and must comply with any applicable federal or state mandates.

The site must maintain a copy of the standing order if administering vaccine pursuant to the order.
Please call the Office of the Commissioner at (804) 864-7001 with questions about the standing order.

Eligible Vaccine Recipients in Virginia*:
*This order is consistent with the FDA Approval and/or FDA EUA for monkeypox vaccine products. As vaccine recommendations are modified, the standing order will be revised. *More information can be found on CDC Monkeypox and Smallpox Vaccine Guidance and CDC Vaccination Strategies.

The following individuals are eligible to receive monkeypox vaccination[↕]:

1) Those who, within the past 14 days, have had an intermediate to high risk exposure to a known and documented monkeypox case
2) Those with certain risk factors and recent experiences that might make them more likely to have been recently exposed to monkeypox:
    a) Person (of any sexual orientation or gender) who has had anonymous or multiple (more than 1) sexual partners in the last 2 weeks
    b) Person (of any sexual orientation or gender) diagnosed with any sexually transmitted infection in the past three months
    c) Person (of any sexual orientation or gender) who is living with HIV/AIDS
    d) Staff (of any sexual orientation or gender) at establishments or events where sexual activity occurs
    e) Sex workers (of any sexual orientation or gender)
3) Those whose jobs may expose them to orthopoxviruses, such as monkeypox; examples include:
    a) Healthcare providers who are administering ACAM2000
    b) Laboratorians handling monkeypox specimens

[↕]**Individuals may attest to meeting one or more of the eligibility criteria for vaccination, however should not be required to attest to a specific criterion nor should they be asked details about their eligibility.**

JYNNEOS

- **FDA Approval/License** was issued in 2019 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. The approved dosing for adults is 0.5 mL administered subcutaneously.
- **Emergency Use Authorization (EUA) was issued on 8/9/22 for:**
    - 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, and
    - 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.
- **Note: Under this Standing Order, JYNNEOS vaccine may be given following the FDA-approved or the FDA EUA-authorized dosing;** see Table 1. below.
- **Safety:**
    - **Contraindications:** Anyone with a known history of an immediate or severe allergic reaction (e.g., anaphylaxis) to a prior dose of JYNNEOS vaccine; DO NOT vaccinate.
    - **Precautions/Warnings:**
        - History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin.
        - History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products.
        - Moderate or severe acute illness, with or without fever.
    - For information on how to address these precautions, and other safety considerations, visit CDC Interim Considerations on Vaccination Safety.

- **Storage and Handling:**
  - For information about JYNNEOS storage and handling, see the JYNNEOS EUA and CDC JYNNEOS Storage and Handling Summary**.**

Table 1. Overview of JYNNEOS vaccine regimens. For more information on dosing, visit the CDC Recommended Dosing Schedule.

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

ACAM2000

- **FDA Approval/License** was issued in 2007 for immunization against smallpox disease for people determined to be at high risk for smallpox infection. It has been made available for the prevention of monkeypox disease under an Expanded Access Investigational New Drug application (EA-IND).
- CDC recommends that vaccination with ACAM2000 can be considered for people aged 1 year and older who have been determined to be at high risk for infection to prevent monkeypox disease. See Table 2. below for the vaccination schedule for ACAM2000.
- **Safety:**
  - ACAM2000 is not recommended for individuals with **severe immunodeficiency** who are not expected to benefit from the vaccine. These individuals may include persons who are undergoing bone marrow transplantation or persons with primary or acquired immunodeficiency states who require isolation. For more details on contraindications and precautions, visit, CDC Contraindications and Precautions for Use of ACAM2000 Vaccine.
  - Adverse events following ACAM2000, including myopericarditis/pericarditis and 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 outweigh any potential risks from ACAM2000 adverse events.
- **Storage and Handling:**
  - For information about ACAM2000 storage and handling, ACAM2000 Package Insert.

Table 2. Vaccination schedule for ACAM2000 vaccine. For more information on dosing, visit the CDC ACAM2000 Vaccine.

ACAM2000 regimen	Route of administration	Injection Volume	Recommended number of doses
People age ≥1 years	Percutaneous, delivered using a bifurcated needle	0.0025 mL droplet of reconstituted vaccine	1 (single dose)

Directions for Use for Monkeypox Vaccines:
Vaccinators should follow the ACIP Vaccine Recommendations and Guidelines for needle length and administration site selection, infection control, and sterile technique. For administration instructions, please refer to the FDA Fact Sheets for each product (**JYNNEOS** | **ACAM2000**).

Post-vaccination Observation and Emergency Protocol:

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
  - **30 minutes**: persons with a history of anaphylaxis due to any cause
  - **15 minutes**: all other persons
- Be prepared to manage a medical emergency resulting from vaccine administration and have written emergency medical protocols, policies, and procedures, as well as medical equipment and medications (such as epinephrine and diphenhydramine) readily available in places where vaccines are provided according to CDC Clinical Considerations for Managing Anaphylaxis. A prescriber may need to issue a standing order for use of these drugs per Virginia Code §54.1-3408 (D).
- Report all adverse reactions, as well as any administration errors, to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 1-800- 822-7967

Documentation Guidelines:

- Vaccination screening and consent must occur prior to vaccination.
- Ensure the dose is entered in the Virginia Immunization Information System (VIIS).
- Record the vaccination date, site, and route; the manufacturer and lot number; and the name of the person administering the vaccine in the patient's record/chart. If the vaccine was not given, document the reason. Document in the patient's record the VIS publication date and the date it was given to the patient.
- Provide the patient (or parent/guardian/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). For the Spanish version: www.immunize.org/vis.
- Schedule 2nd dose, if applicable, 28 days or later from first dose with the goal of getting as close to day 28 as possible.

Prescriber: DocuSigned by: Colin M. Greene 80186E196D924B6... **Date:** 11/2/2022 | 4:59:49 PM EDT

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