MONKEYPOX

# JYNNEOS Smallpox and Monkeypox Vaccine

## STANDARD REGIMEN Standing Orders for Administering Vaccine Subcutaneously

| Vaccine Product | Dose/Injection Amount | Route |
|---|---|---|
| Yellow capped vial with turquoise and white label | Dose: 0.5mL (standard regimen) | **Subcutaneous (Subcut) injection** |

**Note: The 2022 U.S. monkeypox outbreak is rapidly evolving. This document addresses the standard dosing regimen of SUBCUTANEOUS administration of JYNNEOS vaccine only. For this outbreak, the Alternative Regimen administered intradermally is generally the preferred approach for people eligible for monkeypox vaccine who are 18 years of age or older. People eligible for monkeypox vaccine who are 18 years and older and who have history of developing keloid scars or eligible people who are younger than 18 years old are recommended to receive monkeypox vaccine using the Standard Regimen.**

## Purpose

To reduce morbidity and mortality from smallpox and monkeypox by vaccinating people who meet the criteria established by the Centers for Disease Control and Prevention (CDC).

## Policy

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate people who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

## Procedure

- **Assess People for Need of Vaccination** against smallpox and monkeypox based on current guidance provided by CDC and state or local public health authorities. Refer to Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak | Monkeypox | Poxvirus | CDC for current CDC guidance for the 2022 Monkeypox Outbreak. Healthcare professionals must monitor this website for updates and comply with any such posted updates.
- **Screen for Contraindications and Precautions**
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine
  - Precautions:
    - 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
    - After discussing risks and benefits with the patient, people with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination
- **Assess People for Vaccine Dose and Route**
  - Administration of JYNNEOS vaccine is under an Emergency Use Authorization (EUA) for this monkeypox outbreak. JYNNEOS vaccine can be administered either subcutaneously or intradermally depending on the person's age and presence of certain medical conditions. All people younger than 18 years of age and people of any age with a history of developing keloid scars should receive JYNNEOS vaccination subcutaneously. Prior to administration in people younger than 18 years of age, clinicians should first contact their jurisdictional health department (Jurisdictional Contacts) to facilitate consultation with CDC. **Please note that this document addresses subcutaneous administration only.** For intradermal administration see: JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC
- **Provide Vaccine Information Statement (VIS)**
  - Before administering JYNNEOS vaccine, provide a CDC Vaccine Information Statement (VIS) (www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html), or FDA Emergency Use Authorization (EUA) Fact Sheet (www.fda.gov/media/160773/download) for people receiving JYNNEOS vaccine under EUA, as applicable, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. For the Spanish version, refer to the Language Index at www.immunize.org/vis.

- **Prepare to Administer Vaccine**
  - Allow JYNNEOS vaccine to thaw and reach room temperature before use. Frozen vaccine takes approximately 10 minutes to thaw
  - When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension
  - Swirl the vial gently for at least 30 seconds
  - Withdraw dose of 0.5 mL using a 23–25 gauge, 5/8" needle into a sterile syringe for injection
- **Administer Vaccine**
  - **Vaccine Schedule:** Administer two doses of JYNNEOS (0.5 mL each) 28 days (4 weeks) apart
    - For more details on the dosing interval, refer to www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#dosing
  - **For people ≥12 months of age:** Administer JYNNEOS subcutaneously by pinching up fatty tissue over the **triceps** area in the upper arm and insert the needle at a 45-degree angle.
  - **For infants <12 months of age:** Administer JYNNEOS subcutaneously by pinching up fatty tissue over the **anterolateral thigh** and insert the needle at a 45-degree angle.
    - Vaccines inadvertently administered intramuscularly (IM) can be considered valid doses and do not need to be repeated. IM doses need to be reported to the manufacturer at drug.safety@bavarian-nordic.com.
- **Document Vaccination**
  - Document in each vaccine recipient's record Vaccine Administration Data elements as provided in the HHS Monkeypox Vaccination Program Provider Agreement and report these data at least weekly through either
    1. The Immunization Information System (IIS) of the state, local, or territorial jurisdiction or
    2. Another system designated by CDC according to CDC documentation as may be posted on the Provider Agreement update webpage (www.cdc.gov/poxvirus/monkeypox/clinicians/provider-agreement.html).
- **Observe Patients after Vaccination**
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes:** People with a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein (AND who are currently avoiding exposure to all chicken or egg products)
    - **15 minutes:** Can consider for all other people
- **Counsel the patient to return in 28 days (4 weeks) for the second dose if the dose administered is the first dose.**
- **Be Prepared to Manage Medical Emergencies**
  - Vaccine providers should be familiar with identifying immediate allergic reactions, including anaphylaxis, and be prepared to treat these events at the time of vaccine administration.
    - Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction.
    - Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is advised, even after complete resolution of symptoms and signs.
- **Report Adverse Events to VAERS**
  - Vaccination providers are responsible for MANDATORY reporting of the following listed events following JYNNEOS vaccination to VAERS:
    - Vaccine administration errors whether or not associated with an adverse event
    - Serious adverse events (irrespective of attribution to vaccination)
    - Cases of cardiac events including myocarditis and pericarditis
    - Cases of thromboembolic events and neurovascular events
  - Reporting is encouraged for any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event
  - Information on how to submit a report to VAERS is available at vaers.hhs.gov or by calling 1-800-822-7967

## JYNNEOS Vaccine Safety Consultations

CDC's Clinical Immunization Safety Assessment (CISA) Project is available to provide consultation to U.S. healthcare providers and health departments about complex smallpox and monkeypox vaccine safety questions for their patients. In case of an emergent clinical vaccine safety inquiry, U.S. healthcare providers and health department staff can call the CDC Emergency Operations Center (EOC) Watch Desk at (770) 488-7100. For non-emergent issues, healthcare providers can request CISA consultation at CISAeval@cdc.gov.

## Additional Resources

- CDC's Vaccine Administration Resource Library at www.cdc.gov/vaccines/hcp/admin/resource-library.html
- Subcutaneous (Subcut) Injection Administration Video: www.youtube.com/watch?v=R5jd4SDEcsA
- JYNNEOS Subcutaneous Vaccine Preparation and Administration Summary: see Related Resources
- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at www.immunize.org/catg.d/p3082.pdf
- JYNNEOS Vaccine Package Insert at www.fda.gov/media/131078/download

## Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____
effective _____until rescinded or until _____ .

Medical director (or other authorized practitioner)

_____/_____/_____.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders