MONKEYPOX

18 Years of Age and Older

# JYNNEOS Smallpox and Monkeypox Vaccine

## Standing Orders for Administering Vaccine

| Vaccine Product | Dose/Injection Amount | Route |
|---|---|---|
| Yellow capped single-dose vial with turquoise and white label | Dose/Injection Amount | Subcutaneous (Subcut) injection |

**Note: JYNNEOS is currently approved for prevention of smallpox and monkeypox disease in persons 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. CDC is working with FDA to expand eligibility for persons under age 18 years through an Expanded Access Investigational New Drug (EA-IND) Protocol.**

## Purpose

To reduce morbidity and mortality from smallpox and monkeypox by vaccinating persons 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 persons 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 Persons for Need of Vaccination** against smallpox and monkeypox based on current guidance provided by CDC and state or local public health authorities. Refer to www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html for current CDC guidance for the 2022 Monkeypox Outbreak. Health care 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, these persons may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination
- **Provide Vaccine Information Statement (VIS)** Provide all recipients with a copy of the current VIS at www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html. For the Spanish version, refer to the Language Index at www.immunize.org/vis.
- **Prepare to Administer Vaccine**
  - Allow JYNNEOS vaccine to thaw and/or reach room temperature before use. It takes about 10 minutes to thaw from -20°C (-4°F)
  - When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension
  - Swirl the vial gently for at least 30 seconds before use
  - Withdraw dose of 0.5 mL using a 23–25 gauge, 5/8" needle into a sterile syringe for injection
- **Administer Vaccine**
  - Administer JYNNEOS **subcutaneously** into the fatty tissue over the triceps area in the upper arm. Pinch up fatty tissue over the triceps 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
  - Administer two doses of JYNNEOS (0.5 mL each) 28 days apart
    - For more details on the dosing interval, refer to www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html.

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- **Document Vaccination**
  - Vaccination providers must document each recipient's vaccine administration information in their medical record systems within 24 hours of administration and use their best efforts to report data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as possible and no later than 72 hours after administration
  - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, and name and title of the person administering the vaccine
  - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS
- **Observe Patients after Vaccination**
  - 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 Medical Emergencies**
  - Vaccine providers should be familiar with identifying immediate allergic reactions, including anaphylaxis, and be competent in treating 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**
  - Adverse events that occur in a patient following monkeypox or smallpox vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
  - Reporting is encouraged for any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Vaccine administration errors can be reported whether or not associated with an adverse event.
  - Information on how to submit a report to VAERS is available at vaers.hhs.gov or by calling 1-800-822-7967.

## Smallpox and Monkeypox Vaccine Safety Consultations

CDC's Clinical Immunization Safety Assessment (CISA) Project is available to provide consultation to U.S. health care 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. health care providers and health department staff can call the CDC Emergency Operations Center (EOC) Watch Desk at (770) 488-7100.

## 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
- 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