



## Adults with Certain Medical Conditions and Children

# JYNNEOS Smallpox and Monkeypox Vaccine

## Standing Orders for Administering Vaccine Subcutaneously: **STANDARD REGIMEN**

Vaccine Product	Dose/Injection Amount	Route
Yellow capped single-dose 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. Persons 18 years of age and older who have a history of keloid scars should receive JYNNEOS vaccination subcutaneously. Additionally, persons younger than age 18 years should receive JYNNEOS vaccination subcutaneously**

### 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](http://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html) 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, persons with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination

- **Assess Persons for Vaccine Dose and Route**
  - JYNNEOS vaccine can be administered either subcutaneously or intradermally depending on the person’s age and presence of certain medical conditions. All persons less than 18 years of age and persons 18 years of age and older who have a history of keloid scars should receive JYNNEOS vaccination subcutaneously.
  - **Please note that this document addresses subcutaneous administration only.**
- **Provide Vaccine Information Statement (VIS)**
  - Provide persons younger than age 18 with a copy of the [FDA EUA Fact Sheet for Recipients and Caregivers](https://www.fda.gov/oc/ohrt/fda-eua-fact-sheet-for-recipients-and-caregivers). Provide persons 18 years of age and older with a copy of the current VIS at [www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html](http://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](http://www.immunize.org/vis).
- **Prepare to Administer Vaccine**
  - Allow JYNNEOS vaccine to thaw and reach room temperature before use.
  - 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 apart
    - » For more details on the dosing interval, refer to [www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html](http://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html).
  - For persons ≥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](mailto:drug.safety@bavarian-nordic.com).
- **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 jurisdiction’s relevant system (e.g., immunization information system) as soon as possible and no later than 72 hours after administration.
  - Medical record: Record the vaccine name, the date it was administered, manufacturer, lot number, dose administered, vaccination site and route, the name and title of the person administering the vaccine, the publication date of the VIS and the date it was given to the patient.
  - Immunization information system (IIS): Report the vaccination to the appropriate state or local IIS.
  - Personal vaccination record: Provide recipient with card or record that contains date of vaccination, product name and manufacturer, lot number, dose administered, vaccination site and route, and name/location of the clinic or health care professional. Record the date the recipient should return for the second dose.
- **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 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 persons
- **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**
  - Reporting is required for any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Vaccine administration errors should 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](https://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](mailto:CISAeval@cdc.gov).

## Additional Resources

- CDC’s Vaccine Administration Resource Library at [www.cdc.gov/vaccines/hcp/admin/resource-library.html](https://www.cdc.gov/vaccines/hcp/admin/resource-library.html)
- Subcutaneous (Subcut) Injection Administration Video: [www.youtube.com/watch?v=R5jd4SDEcsA](https://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](https://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](https://www.immunize.org/catg.d/p3082.pdf)
- JYNNEOS Vaccine Package Insert at [www.fda.gov/media/131078/download](https://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)

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