**Purpose and Policy**

To reduce morbidity and mortality from monkeypox disease by enabling eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet eligibility criteria for the JYNNEOS vaccine, without the need for examination or direct order by the supervising physician at the time of the encounter.

**Vaccine and Status**

* JYNNEOS approved by FDA in 2019 for **ages 18Y+**
* Smallpox and Monkeypox Vaccine, Live, Attenuated Replication-Deficient Vaccinia Virus
* 2-dose primary series, 28 days apart
* Manufactured by Bavarian Nordic A/S, Denmark

**Vaccine Components**

* No material of direct animal origin
* No preservatives or latex
* Vaccine contains live virus plus residual amounts of host-cell DNA, protein, benzonase, gentamicin, and ciprofloxacin.

**Indications for Vaccination**

**FDA Licensure:** 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.

**PEP Indication:** CDC recommends that JYNNEOS can be given for Post-Exposure Prophylaxis (PEP) of monkeypox within 4 days from the date of exposure to prevent onset of the disease. If given between 4-14 days after the date of exposure, vaccination may reduce the symptoms of disease, but it may not prevent the disease. See [Monkeypox and Smallpox Vaccine Guidance | CDC](https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html)

**PrEP Indication:** CDC recommends JYNNEOS as Pre-Exposure Prophylaxis (PrEP) for persons at occupational risk for exposure to orthopoxviruses including monkeypox. See [MMWR 2022](https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm)

* Research laboratory personnel who directly handle orthopoxvirus-infected specimens or animals, or replication-competent orthopoxvirus strains
* Clinical laboratory personnel performing diagnostic testing for orthopoxviruses
* Healthcare personnel who administer smallpox vaccine or care for patients infected with orthopoxviruses

**Booster Doses**

Persons who are at **ongoing risk for occupational exposure** and who received a primary series with JYNNEOS or with smallpox vaccine (DRYVAX or ACAM2000) should receive JYNNEOS booster dose(s).

* At risk of ongoing exposure to smallpox or monkeypox virus: booster every 2 years
* At risk of ongoing exposure to vaccinia or cowpox virus: booster at least every 10 years.

**Vaccine Storage & Preparation**

JYNNEOS is a suspension for injection, with each 0.5-mL dose supplied in a single-dose vial.

* **Store frozen** at -25°C to -15°C (-13°F to +5°F) until expiration date on vial label.
* **Store refrigerated** at 2°C-8°C for up to 8 weeks (this differs from package insert – see [Provider Letter](https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf)).
* Store in original package to protect from light.
* Allow vaccine to thaw and reach room temperature before use.
* Once thawed, may be kept in refrigerator at +2°C to +8°C (+36°F to +46°F) for **12 hours**. Don’t refreeze.

**Vaccine Administration**

Primary series: 0.5 mL SQ at 0 and 28 days

* When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.
* Inspect visually for particulate matter and discoloration prior to administration, and do not administer if present
* Swirl the vial gently before use for at least 30 sec.
* Withdraw a dose of 0.5 mL into a sterile syringe and administer by subcutaneous (SQ) injection.
* Administer 2nd dose 28 days later.

**Contraindications**

Per CDC, JYNNEOS is contraindicated in persons with serious allergy to a vaccine component, including persons who had a severe allergic reaction following a previous dose of JYNNEOS.

**Warnings & Precautions**

**Allergic reactions.** Since severe allergic reactions to JYNNEOS are possible, appropriate medical treatment (epinephrine, oxygen) must be available to manage possible anaphylactic reactions. Risk for a severe allergic reaction should be weighed against the risk for disease due to smallpox or monkeypox.

**Immunocompromised Persons**

JYNNEOS is safe to administer to immunocompromised persons; however, they may have a diminished immune response to the vaccine.

**Pregnancy**

Data are insufficient to determine vaccine-associated risks in pregnancy. In animals who received JYNNEOS, there has been no evidence of harm to the developing fetus.

**Breastfeeding**

It is not known whether JYNNEOS is excreted in human milk or is safe in breastfed infants. However, per CDC it is unlikely to present a risk of transmission to breastfed infants and can be administered to women who are breastfeeding if vaccination is critical.

**Adverse Events**

Common adverse reactions include

* Pain, redness, swelling, itching, and/or induration at the injection site
* Myalgia, fatigue, headache, nausea, and/or chills
* Fever is uncommon

In clinical trials, serious adverse events were rare and occurred in JYNNEOS recipients at about the same frequency as those who received placebo.

Clinical studies did not detect an increased risk for myocarditis among JYNNEOS recipients. However, per CDC, persons with underlying heart disease or 3 or more major cardiac risk factors should be counseled about the theoretical risk for myocarditis following JYNNEOS.

**Timing With COVID-19 Vaccine**

CDC recommends that adolescent or young adult males should consider waiting 4 weeks after JYNNEOS vaccination before receiving an mRNA COVID-19 vaccine due to theoretical concerns regarding myocarditis. If JYNNEOS is recommended for PEP in an outbreak setting, administration of JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine. No other vaccine-vaccine interactions are noted to be of concern.

**Development of Immunity**

Peak antibody response is achieved 2 weeks after the second dose of the 2-dose JYNNEOS series. Rates of seroconversion are high; therefore, for immunocompetent persons, effective vaccination can be assumed. Routine antibody titer testing after JYNNEOS is not recommended.

**Replication-Deficient Vaccine**

The live, attenuated (weakened) vaccinia virus in JYNNEOS is replication-deficient and does not cause clinical infection in recipients.

JYNNEOS, as a replication-deficient vaccine, does not require precautions associated with other live vaccines.

**Additional Information**

Provide [current VIS](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html) prior to vaccine administration

Report clinically significant adverse events to [VAERS](https://vaers.hhs.gov/index.html).

**For More Information**

[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 | MMWR (cdc.gov)](https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm)

[Information For Clinicians | Monkeypox | Poxvirus | CDC](https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html)

**Authorization**

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Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name – Title

**APPENDIX**

**Equipment**

* Monkeypox (JYNNEOS) vaccine
* Syringes
* 22-25 gauge, 5/8-inch needle
* Portable vaccine refrigerator, purpose-built unit, hard-sided cooler or Styrofoam insulated coolers
* Bubble wrap
* Corrugated cardboard
* Cold packs or frozen water bottles
* Monkeypox Vaccination Consent Form, per local standard
* [Vaccine Information Statement](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf)
* Emergency Cart/Anaphylaxis kit
* Fluid-resistant isolation gown
* Gloves
* N95 respirator
* Goggles/Face Shield
* Sharps container
* Trash bags
* Pens
* Hand sanitizer (if no water and soap available)

**Procedure – See Procedure Flowchart below**

1. Staff reviews physician order for Monkeypox (JYNNEOS) vaccine. Does client meet the recommendations for the Monkeypox (JYNNEOS) vaccine?
2. If the client has an order for the Monkeypox (JYNNEOS) vaccine and meets the recommendation, staff proceeds to Step 2. Note: Clients < 18 years old will be evaluated by [*describe reviewing health department staff here*] for JYNNEOS vaccine administration.
3. If client does not meet the recommendation for the Monkeypox (JYNNEOS) vaccine, no staff action needed at this time.
4. Note: Client shall wear a well-fitting surgical mask during Monkeypox (JYNNEOS) vaccine administration.
5. Staff screens for contraindications and warnings and precautions as described above.
6. If the client does not have any contraindications for the Monkeypox (JYNNEOS) vaccine, staff will proceed to Step 3.
7. If the client does have contraindications to the Monkeypox vaccine staff will not administer the Monkeypox vaccine and refer client to his/her/their primary care provider.
8. Staff discusses Monkeypox (JYNNEOS) vaccine administration, provides education to the client/legal guardian, and obtains consent.
9. Provides the client/guardian with a copy of the [Smallpox/Monkeypox (JYNNEOS) VIS](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf). Allow sufficient time to read the VIS as well as any necessary materials and consent forms. Take time to answer the client/ guardian's vaccine related question.
10. Staff performs hand hygiene using soap and water or alcohol-based hand sanitizer (containing 60 to 95% alcohol) for at least 20 seconds.
11. Staff adheres to standard precautions and applies personal protective equipment (PPE) (e.g., medical grade facemask, goggles/full face shield, gloves and if applicable gown) following [PPE donning and doffing sequence](https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf).
12. Staff identifies the client per standard practice protocols.
13. Staff prepares vaccine following Vaccine Storage & Preparation and Vaccine Administration as per above.
14. Confirm there are no other particulates and that no discoloration is observed in the thawed vial. Do NOT administer if vaccine is discolored or contains other particulate matter.
15. Swirl the vial gently for at least 30 seconds before use.
16. Use a 22–25-gauge 5/8-inch needle to administer vaccine.
17. Withdraw a dose of 0.5 mL into a sterile syringe for injection. Verify final dosing volume of 0.5 mL.
18. Do NOT dilute the vaccine.
19. Staff administers Monkeypox vaccine [following CDC best practices](https://www.youtube.com/watch?v=R5jd4SDEcsA&ab_channel=CentersforDiseaseControlandPrevention%28CDC%29):
20. Administer JYNNEOS by subcutaneous injection (SQ), typically into the upper arm.
21. Each dose must contain 0.5 mL of vaccine.
22. To prevent syncope, vaccinate client while they are seated.
23. Post administration of vaccine, monitor the client for adverse reactions, including anaphylaxis.
	1. **If client experiences an anaphylactic reaction, immediately respond by following** [**CDC guidance**](https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf)**.**

1. Staff shall doff PPE (see [donning and doffing sequence](https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf)) and performs hand hygiene using soap and water for at least 20 seconds or alcohol-based hand sanitizer that contains 60 to 95% alcohol.
2. Staff stores and handles Moneypox (JYNNEOS) vaccine per manufacturer’s procedures. (See above.)
3. If the staff has any questions, staff will contact [*describe contact/supervisor here*].

1. Staff documents vaccine administration in [*describe preferred records system here*].
2. Give patient a Yellow Card with the date and clinic (Health Center) where vaccine was administered. If vaccine is administered in the field, use the [*describe local site preference here*] as the vaccination site.
	1. Review recommendation for second dose. Inform patient to return in 28 days for the second dose of JYNNEOS vaccine.
3. Document any adverse reaction(s) in VAERS, including actions taken to address the reaction(s) if applicable.
4. Review possible reactions to the vaccine. Report incident to your supervisor per practice protocols.
5. Report adverse reactions to the [Vaccine Adverse Events Reporting System (VAERS)](https://vaers.hhs.gov/reportevent.html) via mail, FAX, or internet.
6. Document administration as [per CDC guidance](https://www.cdc.gov/vaccines/hcp/admin/document-vaccines.html):
7. Date of administration
8. Manufacturer name
9. Lot number
10. Vaccination site and route
11. Name and title of the person administering the vaccine

**Procedure Flowchart**

