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4th REVISED STANDING ORDER FOR MPOX VIRUS VACCINE - JYNNEOS®

Control Number: 2025-001

Monkeypox (mpox) is a disease caused by infection with the mpox virus. Mpox belongs to the *Orthopoxvirus* genus in the family *Poxviridae*. The *Orthopoxvirus* genus also includes variola virus (which causes smallpox), vaccina virus (used in the smallpox vaccine), and cowpox virus. Mpox is a disease with symptoms that are similar to but milder than the symptoms of smallpox.

JYNNEOS® is approved by the Federal Drug Administration (FDA) and recommended by the Advisory Committee on Immunization Practices (ACIP) for the prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for mpox infection. The standard regimen for JYNNEOS® involves a subcutaneous (Subcut) route of administration with an injection volume of 0.5mL. An alternative regimen involving intradermal (ID) administration with an injection volume of 0.1mL may be used under an Emergency Use Authorization (EUA) (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#monkeypox). JYNNEOS® is available for use as post exposure prophylaxis for children and adolescents <18 years of age determined to be at high risk for mpox infection under the EUA; vaccination for children and adolescents age < 18 years should be administered via Subcut injection.

In May 2022, the Centers for Disease Control and Prevention (CDC) identified an outbreak of mpox in the United States. As of July 2022, New Jersey identified cases of mpox disease among its residents. In order to protect people against mpox, the Department of Health (DOH) issued a standing order for Subcut vaccination of persons ≥18 years with JYNNEOS® who were at high risk for exposure.

On August 9, 2022, the FDA issued the EUA to allow healthcare providers to use the vaccine by ID administration and to allow Subcut administration to persons <18 years determined to be at high risk for mpox infection. The orders were revised to reflect this updated information.

As of April 1, 2024, the vaccine is commercially available in the United States. Providers may continue to access JYNNEOS® through the New Jersey Department of Heath until the supply is exhausted or the doses expire, whichever comes first.

On December 23, 2024, the FDA reviewed and revised the EUA for JYNNEOS®. The updated EUA continues to allow administration of JYNNEOS®to children <18 years of age and to adult ≥18 years of age and older by the intradermal route.

The previously issued order is hereby revised to reflect the most updated information.

Purpose:
To reduce the morbidity and mortality from mpox by vaccinating eligible persons who meet the criteria established by the CDC and the New Jersey Department of Health.

Authorization:
This standing order enables New Jersey-licensed or certified healthcare professionals who are eligible to administer vaccinations under State law to assess the need for vaccination and to vaccinate persons with JYNNEOS® who are eligible for vaccination. This standing order authorizes persons to vaccinate using JYNNEOS® obtained through the New Jersey Department of Health and not through commercial channels (e.g., directly from the manufacturer, distributor).

Procedure:

1) Read the Interim Clinical Considerations for Use of JYNNEOS® Vaccine for Mpox Prevention in the United States, the JYNNEOS® package insert, and the FDA EUA Fact Sheet for Providers available at https://www.cdc.gov/poxvirus/mpox/clinicians/vaccines/vaccine-considerations.html and the information on the DOH website at https://www.nj.gov/health/monkeypox/health-professionals/. Healthcare providers are responsible for monitoring these websites for updates and comply with any such posted updates.
2) Assess current smallpox/mpox vaccination status of patient.
3) Screen for contraindications and precautions. (see Section 5 below)
4) Have a plan in place, supplies, and trained personnel available to provide appropriate medical care to address adverse vaccine reactions should they occur. Please see https://www.immunize.org/clinical/topic/managing-vaccine-reactions/. Report adverse events to the Vaccine Adverse Event Reporting System (VAERS) (see Section 4 below)
5) Prior to administration, provide the patient or caregiver with the current Fact Sheet for Patients JYNNEOS®_EUA-FactSheetForRecipientsAndCaregiversTemplate-rev-Dec-2024.pdf and Caregivers or Vaccine Information Sheet (VIS) available at https://www.cdc.gov/vaccines/hcp/current-vis/smallpox-monkeypox.html
6) Discuss the options for vaccine administration for persons ≥18 years (Subcut vs ID) and prepare and administer JYNNEOS® in accordance with Section 1 and Section 2 below.
7) Observe the vaccine recipient for adverse events for at least 15 minutes following vaccine administration. (see Section 5 below)
8) Record all required elements in the vaccine recipient's record. Provide vaccine recipient with documentation of vaccination.
9) Doses of JYNNEOS® administered pursuant to this standing order must be entered into the New Jersey Immunization Information System (NJIIS) in the manner set forth in N.J.S.A. 26:4-134, N.J.A.C. 8:57-3.12, and Executive Order 207 (Murphy). Information and forms website are available on the NJIIS website at https://njiis.nj.gov/core/web/index.html#/home

Section 1. Vaccination Schedule and Dosing Regimens for JYNNEOS® Vaccine
The vaccine is licensed as a series of two doses administered 28 days (4 weeks) apart.

The standard regimen involves a Subcut route of administration with an injection volume of 0.5mL. The standard regimen is the FDA- approved dosing regimen. Since August 9, 2022, the

standard regimen has also been authorized for people < 18 years under an EUA.

An alternative regimen may be used for people aged ≥18 years under an EUA which was issued on August 9, 2022, to make more doses available when vaccine supply was limited. The authorized alternative regimen involves an ID route of administration with an injection volume of 0.1mL.

Either the standard or alternative regimen may be used for people ≥18 years. Both the standard (Subcut) and the alternative (ID) regimen have been found to be effective for mpox prevention.

- There is currently adequate supply of JYNNEOS® vaccine. Therefore, clinicians can preferentially administer JYNNEOS® via the Subcut route.

JYNNEOS® vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd doses+
≥18 years	Subcut over triceps	0.5mL	2	28 days
≥18 years	ID volar aspect of forearm or back	0.1mL	2	28 days
1 year through 17 years*	Subcut over triceps	0.5mL	2	28 days

*Please note that administration of JYNNEOS® to persons <1 year of age is not covered by this standing order. Consult the child's healthcare provider for appropriate management of children <1 year.
+People should understand the importance of returning for the second dose to ensure optimal protection and be given an appointment for the second dose, if possible.

Section 2.
Preparation

- JYNNEOS® received through the New Jersey Department of Health is a single dose vial that does not require reconstitution before use. NOTE: a two-vial presentation of lyophilized vaccine and diluent is available commercially.
- 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
- For Subcut injection - Withdraw dose of 0.5mL using a 23 – 25 gauge, 5/8" needle into a sterile syringe
- For ID injection – Withdraw dose of 0.1mL using 26 – 27 gauge, ¼" – ½" needle with a short bevel into a sterile syringe

Administration

- People ≥12 months through 17 years –
    - Administer JYNNEOS® Subcut by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle
- People ≥ 18 years
    - Administer JYNNEOS® Subcut by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle

OR

- Administer JYNNEOS® ID into the volar surface of the forearm, upper back, or over the deltoid. Pull the skin taut, position the needle with the bevel facing up and insert the needle at a 5 – 15 degree angle into the dermis. A noticeable pale elevation of the skin (wheal) is desirable but not required.

Infection Prevention

- Providers should adhere to Standard Precautions and the principles of Safe Injection Practices including the use of a sterile, single-use, disposable syringe and needle for each injection given, and prevention of contamination of injection equipment and medication. Use a single-use, sterile alcohol swap to clean the vial septum prior to accessing the septum with a needle. Do not use a common source alcohol bottle. Allow the alcohol to dry completely before piercing the septum.
- Never pool the contents of multiple vials
- See the following resources for further information, including on how to safely store, prepare, and administer vaccines:
  - CDC/ACIP General Best Practices for Immunization
  - Epidemiology and Vaccine Preventable Diseases (CDC Pink Book)

Section 3: Vaccine Storage and Handling

- Vaccines must be stored, handled and transported in accordance with the information in the FDA package insert, EUA Fact Sheet for Healthcare Providers and the CDC Vaccine Storage and Handling Toolkit
- Keep the vaccine frozen at -25°C to -15°C
- Store in the original package to protect from light
- Do not re-freeze a vial once it has been thawed
- Once thawed, the vaccine may be kept at +2°C to +8°C for up to 4 weeks. Mark the vials with the beyond-use date (BUD) once thawed.
- Do not use the vaccine vial after the BUD or after the expiration date shown on the vial label

Section 4. Required Reporting for Adverse Events and Vaccine Administration Errors

- Vaccination providers who are administering JYNNEOS® are required to report the following adverse events that occur after JYNNEOS® vaccination:
  - 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; and/or
  - Cases of thromboembolic events and neurovascular events
- Information on how to submit a VAERS report is available at www.vaers.hhs.gov or calling 1-800-822-7967
- Please refer to the FDA EUA Fact Sheet for Healthcare Providers and additional information about the EUA on the FDA website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Section 5. Contraindications and Precautions/Observation Following Vaccination

- **Contraindications**
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose, or to a vaccine component. See the package insert for a full list of ingredients.
  - History of developing keloid scars
- **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 product
  - 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 to an allergist-immunologist for consultation.
- **Observation Following 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: For all other persons

Section 6: Vaccine Side Effects

- Local side effects include redness, pain, swelling, itching, hyperpigmentation, and induration. Systemic effects include fatigue, headache, muscle aches, nausea, chills and fever
- Local side effects may be more severe with ID administration. There have been reports of prolonged induration and erythema following ID injection. Side effects are usually self-limiting

Section 7: Other considerations

Coadministration of JYNNEOS® with other vaccines

- Currently, there are no data on administering JYNNEOS® vaccine at the same time as other vaccines. Because JYNNEOS® is based on a live, attenuated non-replicating orthopoxvirus, JYNNEOS® typically may be administered without regard to timing of most other vaccines. This includes simultaneous administration of JYNNEOS® and other vaccines, including influenza vaccine, on the same day, but at different anatomic sites if possible.
- There is no required minimum interval between receiving any COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) and JYNNEOS® vaccine, regardless of which vaccine is administered first. People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and the hypothetical risk for myocarditis and pericarditis after JYNNEOS® vaccine. However, if a patient is at increased risk for mpox or severe disease due to COVID-19 disease, administration of JYNNEOS® and COVID-19 vaccines should not be delayed.

- Best practices for multiple injections include:
    - Label each syringe with the name and the dosage of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable
    - Administer each injection in a different injection site; separate sites by ≥1 inch
    - Administer the JYNNEOS® vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible

Pregnancy and Lactation

- Available human data on JYNNEOS® administered to people who are pregnant are insufficient to determine if there are any vaccine-associated risks in pregnancy. Studies of JYNNEOS® vaccine in animals have shown no evidence of harm to a developing fetus.
- While there are no data for people who are breastfeeding, animal data do not show evidence of reproductive harm; breastfeeding is not a contraindication to receiving JYNNEOS®. It is not known whether JYNNEOS® is excreted in human milk. Data are not available to assess the impact of JYNNEOS® on milk production or the safety of JYNNEOS® in breastfed infants. However, because JYNNEOS® vaccine is replication-deficient, it likely does not present a risk of transmission to breastfed infants.
- JYNNEOS® can be offered to people who are pregnant or breastfeeding who are otherwise eligible. The risks and benefits of JYNNEOS® should be discussed with the patient using shared clinical decision-making.

Pediatric Use

- Adolescents at risk for mpox may receive the JYNNEOS® vaccine before an exposure. JYNNEOS® is available for use as post exposure prophylaxis (PEP) for children and adolescents <18 years determined to be at high risk for mpox under the Emergency Use Authorization (EUA) issued by the US Food and Drug Administration. Vaccination with JYNNEOS® for children and adolescents aged <18 years should be administered via subcutaneous injection.
- For patients <6 months of age, Vaccinia Immune Globulin Intravenous (VIGIV) should be considered in lieu of JYNNEOS® vaccine. DOH can facilitate consultation with CDC and access to VIGIV. The administration of VIGIV is not covered by this standing order.
- Please note that administration of JYNNEOS® to persons <1 year of age is not covered by this standing order. Consult the child's healthcare provider for appropriate management of children <1 year.

Altered immunocompetence

- JYNNEOS® is safe to administer to persons with altered immunocompetence. However, persons who are immunocompromised might have diminished immune response to JYNNEOS®.

Term

This Revised Standing Order supersedes the Standing Order issued on August 13, 2024.

The Revised Standing Order shall take effect immediately and remain in force and effect until modified, supplemented, superseded, rescinded.

New Jersey Department of Health Issuing Official

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Public Health Services
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