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2nd REVISED STANDING ORDER FOR MONKEYPOX (MPXV) VIRUS VACCINE - JYNNEOS™

Control Number: 2022-001 (2nd REVISED)

Monkey pox is a rare disease caused by infection with the monkeypox virus (MPXV). MPXV 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. Monkeypox is a rare disease with symptoms that are similar to but milder than the symptoms of smallpox.

According to the Centers for Disease Control and Prevention (CDC), when properly administered before an exposure, vaccines are effective at protecting people against MPXV disease. Smallpox and MPXV vaccines are effective at protecting people against MPXV disease when given before exposure to MPXV. Experts also believe that vaccination after MPXV exposure may help prevent disease or make it less severe. JYNNEOS™ (also known as Imvamune or Imvanex) is one of two currently licensed vaccines in the United States to prevent smallpox and MPXV disease.

As of July 2022, New Jersey has confirmed and suspect cases of MPXV disease among its residents. In order to protect people against MPXV, the Department of Health (DOH) issued a standing order for subcutaneous vaccination of persons 18 years of age and older with JYNNEOS™ who were at high risk for exposure.

On August 9, 2022, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the JYNNEOS™ vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at risk for MPXV infection. The EUA also allows for the use of the vaccine in individuals younger than 18 years of age determined to be at high risk of MPXV infection; in these individuals, JYNNEOS™ is administered by the standard subcutaneous route.

The previously issued order (Control Number: 2022-001) is hereby revised to reflect this new information.

Purpose:
To reduce morbidity and mortality from MPXV by vaccinating eligible persons who meet the criteria established by the CDC and DOH.

Authorization:
This standing order enables NJ-licensed or certified healthcare professionals who are elilgible to administer vaccination under NJ state law to assess the need for vaccination and to vaccinate persons with JYNNEOS™ who meet the established criteria in NJ.

Procedure:

1) Determine eligibility for pre-exposure or post-exposure MPXV vaccination – screen for eligibility for JYNNEOS™ based on current guidance provided by CDC and DOH. Refer to https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html and https://www.nj.gov/health/cd/topics/monkeypox.shtml for current guidance. Healthcare professionals must monitor these websites for updates and comply with any such posted updates.
2) Assess current smallpox/MPXV vaccination status of patient
3) Read the Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of JYNNEOS™ available at https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html
4) Screen for contraindications and precautions. See Section 5.
5) Have a plan in place and supplies available to provide appropriate medical care to address adverse vaccine reactions should they occur. Please see https://www.immunize.org/catg.d/p3082a.pdf and https://www.immunize.org/catg.d/p3082.pdf.
   Report adverse events to the Vaccine Adverse Event Reporting System (VAERS) – see Section 4
6) Prior to administration, provide the patient with current Fact Sheet for Patients and Caregivers available at https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html. Answer all questions.
7) Prepare and administer JYNNEOS™ if indicated in accordance with Section 1 and Section 2.
8) Observe the vaccine recipient for adverse events for at least 15 minutes following vaccine administration. See Section 5
9) Record all required elements in the vaccine recipient's record.
10) Provide vaccine recipient with documentation of vaccination.
11) Doses of JYNNEOS™ administered must be entered into the New Jersey Immunization Information System (NJIIS) within 72 hours of administration. For vaccine recipients born prior to 1998 and are not in NJIIS, a Consent Form for inclusion must be obtained. The IMM-32 Consent Form is available at https://njiis.nj.gov/core/web/index.html#/njiisDocs

Section 1. Vaccination Schedule and Dosing Regimens for JYNNEOS™ Vaccine

JYNNEOS™ vaccine regimen	Route of administration	Injection Volume	Recommended number of doses	Recommended interval between 1st and 2nd doses*
People age ≥18 years	Intradermal volar aspect of forearm[#]	0.1mL	2	28 days
People age 1 through 17 years	Subcutaneous in upper arm	0.5mL	2	28 days
People of any age who have a history of developing keloid scars[+]	Subcutaneous in upper arm	0.5mL	2	28 days

**Recommended interval:* The second dose of JYNNEOS vaccine should be given 28 days after the first dose. Based on available clinical study data [13 MB, 93 pages], the second dose may be given up to 7 days later than the minimum interval of 28 days (i.e., up to 35 days after the first dose).

Minimum interval: The vaccine manufacturer advises against giving the second dose before the minimum interval of 28 days. However, based on ACIP's general best practices, a dose may be administered up to 4 days before the minimum interval of 28 days (known as the "grace period," which would be a minimum of 24 days after the first dose). Vaccine doses should not be administered before the minimum interval. Nevertheless, if the second dose is inadvertently administered before the minimum interval, the dose may not need to be repeated. Please refer to "Table 7. Vaccine Administration Errors and Deviations."

Maximum interval: If the second dose is not administered during the recommended interval, it should be administered as soon as possible based on ACIP's general best practices. There is no need to restart or add doses to the series if there is an extended interval between doses.

[#]Alternate site is upper back below the scapula for people who cannot receive on the volar aspect of the forearm

[+]People of any age can receive the vaccine subcutaneously if, in the opinion of the licensed healthcare professional administering the vaccine, there is a compelling reason (e.g., 2 failed intradermal attempts, person cannot cooperate due to behavioral issues).

Section 2. Preparation and Administration

JYNNEOS™ is a live, non-replicating virus vaccine. It is a suspension for injection. Each vial contains a single dose (0.5mL) for subcutaneous injection in persons < 18 years of age or up to 5 doses (0.1mL each) for intradermal injections in persons 18 years of age and older.

1) Allow the vaccine to thaw and/or reach room temperature before use (about 10 minutes to thaw from -20° C).
2) When thawed, JYNNEOS™ is a milky, light yellow to pale white colored suspension
3) Swirl the vial gently for at least 30 seconds before use
4) Cleanse the vial stopper with a new, single-use, antiseptic swab before each use and allow the septum to dry

Providers should adhere to Standard Precautions and the principles of Safe Injection Practices, including the use of a sterile, single-use, disposable needle and syringe for each injection given, and prevention of contamination of injection equipment and medication.

See the following resources for further information, including on how to safely store, prepare, and administer vaccines:

- ACIP's general best practices and Epidemiology and Prevention of Vaccine-Preventable Diseases (CDC Pink Book) and

- CDC's Vaccine Administration Tools and
- CDC's One and Only Campaign and FAQs regarding safe injection practices like preparation, administration, and handling of single-dose vials.

Subcutaneous injection for persons 1 through 17 years of age[+]
Withdraw a dose of 0.5mL into a sterile syringe for injection. Administer the vaccine by subcutaneous injection, preferably in the upper arm. Please note in Section 1 that keloid formers of any age may receive the vaccine via the subcutaneous route.

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 of age.

[+]People of any age can receive the vaccine subcutaneously if, in the opinion of the licensed healthcare professional administering the vaccine, there is a compelling reason (e.g., 2 failed intradermal attempts, person cannot cooperate due to behavioral issues).

Intradermal injection for persons 18 years of age and older
Withdraw a dose of 0.1mL into a sterile syringe for injection. Low dead volume syringes and/or needles can be used to extract 5 doses (0.1mL each) for intradermal injection from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 5 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.1mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.1mL, discard the vial and its contents
- **Do not pool excess vaccine from multiple vials**
- Once the vial is punctured and a dose withdrawn, if it is not used in its entirety, it should be stored in the refrigerator at +2 to +8° C and discarded within 8 hours of the first puncture.

Section 3: Vaccine Storage and Handling

- Vaccines must be stored, handled and transported in accordance with the information in the FDA EUA Fact Sheet for Healthcare Providers and the CDC Vaccine Storage and Handling Toolkit at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- Keep frozen at -25 to -15° C (-13 to +5° F). Vaccines maintained in the freezer can be used until the manufacturer's expiration date.
- Store in the original package to protect from light.
- **Do not re-freeze a vial once it has been thawed.**
- Once thawed, the unpunctured vaccine vials may be kept at +2 to +8° C for up to 8 weeks (this information is different from what is in the EUA Fact Sheet for Healthcare Providers). Please see the CDC at https://www.cdc.gov/poxvirus/monkeypox/pdf/Storage-and-Handling-Summary.pdf. Mark the vials with the appropriate beyond-use-date/time when the vials are thawed and placed in the refrigerator.

- After first puncture, vial can be stored at +2 to +8° C for up to 8 hours. Mark the vial with the appropriate beyond-use date/time when vial is first punctured.

Section 4: Required Reporting for Adverse Events and Vaccine Administration Errors
Vaccination providers who are administering JYNNEOS™ under the EUA 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
- Cases of thromboembolic events and neurovascular events

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

Please refer to the FDA EUA Fact Sheet for Healthcare Providers for additional information about reporting requirements.

Section 5: Contraindications and Precautions

- Contraindication
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS™ vaccine
- Precaution
  - 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, the person may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination

Section 6: Vaccine Side Effects
Recipients should be counseled about possible side effects from vaccination including injection site pain, redness, swelling, induration, itching, fatigue, headache, nausea, chills, and muscle aches, and be provided with a JYNNEOS™ vaccine information statement (VIS) or FDA JYNNEOS™ EUA Fact Sheet, as applicable. There have been reports of prolonged duration of induration or erythema following intradermal administration. Side effects are usually self-limiting.

Section 7: Other considerations
Co-administration 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 other vaccines. This includes simultaneous administration of JYNNEOS™ and other vaccines on the same day, but at different anatomic sites if possible.

However, there are additional considerations if administering a COVID-19 vaccine. (Interim Clinical Considerations for Use of COVID-19 Vaccines)

- If an *Orthopoxvirus* vaccine is offered for prophylaxis in the setting of an *Orthopoxvirus* (e.g., monkeypox) outbreak, *Orthopoxvirus* vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and *Orthopoxvirus* vaccination is necessary.
- People, particularly adolescent or young adult males, might consider waiting 4 weeks after *Orthopoxvirus* vaccination (either JYNNEOS™ or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine, because of the observed risk for myocarditis and/or pericarditis after receipt of ACAM2000 *Orthopoxvirus* vaccine and mRNA (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and/or pericarditis after JYNNEOS™.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) 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 injection sites by 1 inch or more, if possible.
- Administer the JYNNEOS™ vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible.

Review ACIP's general best practices and Epidemiology and Prevention of Vaccine-Preventable Diseases (CDC Pink Book) for further information.

Pregnancy
Available human data on JYNNEOS™ administered to pregnant women are insufficient to determine vaccine-associated risks in pregnancy. However, animal models have shown no evidence of harm to the developing fetus

Lactation
It is not known whether JYNNEOS™ is excreted in human milk. Data are not available to assess the effects of JYNNEOS™ in the breastfed infant or on milk production/excretion. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for JYNNEOS and any potential adverse effects of the breastfed child from JYNNEOS™ or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by vaccine.

Pediatric Use
The safety and effectiveness of JYNNEOS™ have not been assessed in individuals < 18 years of age. The FDA has granted an EUA for an emergency use of JYNNEOS™ for active immunization by subcutaneous injection for prevention of monkeypox disease in individuals < 18 years of age determined to be at high risk for infection. The authorization is based on safety and effectiveness

data from clinical trials in adults and efficacy data from animal challenge studies and historical data with use of live vaccinia virus smallpox vaccine in pediatric populations.

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

Persons with Multiple Cardiac Risk Factors
Presence of three or more of these major cardiac risk factors is a contraindication to vaccination with ACAM2000: hypertension, diabetes, hypercholesterolemia, heart disease at age ≤50 years in a first-degree relative, or smoking. Clinical studies have not detected an increased risk for myopericarditis in recipients of JYNNEOS™. However, people with underlying heart disease (e.g., previous myocardial infarction, angina, congestive heart failure, cardiomyopathy, stroke or transient ischemic attack, or other heart conditions) or three or more major cardiac risk factors should be counseled about the theoretical risk for myopericarditis following vaccination with JYNNEOS™ given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccines such as ACAM2000.

Term

This Revised Standing Order supersedes the Standing Order issued on August 15, 2022.

This 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

Margaret C Fisher

9/6/22

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