NEW YORK STATE OF OPPORTUNITY. Department of Health

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Non-Patient Specific Standing Order for the Administration of the JYNNEOS vaccine via Subcutaneous Administration by Pharmacists for Persons Aged 18 and Older (Updated 9/5/2024)

Purpose: To reduce morbidity and mortality from mpox (previously referred to as 'monkeypox') by administering the JYNNEOS vaccine as permitted by the policy and order sections of this Order. Pursuant to 8 NYCRR § 63.9, the Commissioner of Health is authorized to issue a statewide standing order where he finds that there is an outbreak of disease, or that there is imminent threat of an outbreak of disease.

Policy: Under this non-patient specific standing order, pharmacists who are employees, volunteers, and/or contractors of all pharmacies licensed in New York State and who are pharmacists authorized to administer vaccines pursuant to a certificate of administration from the Department of Education under non-patient specific orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the JYNNEOS vaccination to eligible individuals, as permitted by its Biologics License Application (BLA) approval by the U.S. Food and Drug Administration (FDA), Emergency Use Authorization (EUA), PREP Act Declaration for Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses, state and federal laws, Advisory Committee on Immunization Practices (ACIP) recommendations, and the CDC's and New York State's Vaccination Program.

NOTE: Pharmacists must follow the requirements set forth in 8 NYCRR § 63.9, including providing patients with requisite information, maintaining adequate records and adhering to reporting requirements.

Target Population:
JYNNEOS® vaccine is licensed to prevent mpox and recommended by the ACIP for certain people at risk for exposure to mpox.[1] The ACIP recommends the 2-dose JYNNEOS series to several populations and for different indications:

- For people aged 18 years and older at risk of mpox during an mpox outbreak.[2]
- For people aged 18 years and older with the following risks[3]:
    - Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:

[1] JYNNEOS is also licensed to prevent smallpox and recommended for certain people at risk for exposure to orthopoxvirus infections.
[2] Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated include ongoing risk of introduction of mpox into a community due to disease activity in another geographic area. The mpox outbreak that started in 2022 is still ongoing.
[3] This recommendation is on the CDC's Adult Immunization Schedule (for people 19 years of age and older) and Child & Adolescent Immunization Schedule (for people 18 years of age).

- A new diagnosis of ≥1 sexually transmitted disease,
- More than one sex partner,
- Sex at a commercial sex venue, and/or
- Sex in association with a large public event in a geographic area where mpox transmission is occurring.

- Sexual partners of people with the risks described above.
- People who anticipate experiencing or participating in any of the above.

Procedure:
This standing order is for use of JYNNEOS vaccine for subcutaneous injection in two doses (0.5 mL each) to be given 28 days apart in all persons determined to be at risk for mpox infection. Administration of additional JYNNEOS vaccine doses (more than 2 doses) is currently not recommended.

1. **Assess for eligibility of vaccination** against mpox. Assess eligible persons for the JYNNEOS vaccine subcutaneous injection based on the following criteria:
   a. No JYNNEOS vaccine: Administer the first dose of JYNNEOS vaccine according to the procedure described herein.
   b. One (1) previous dose of JYNNEOS vaccine: Administer the second JYNNEOS vaccine 28 or more days after the date of administration of the first vaccine:
   c. JYNNEOS is safe to administer to persons with immunocompromising conditions; however, persons with immunocompromising conditions might be less likely to mount an effective response after any vaccination.

2. **Screen for Contraindications and Precautions:**
   a. **Contraindications:** Do not administer the JYNNEOS vaccine to anyone who has had:
      i. Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine.
   b. **Precautions:** Consider deferral of vaccination with JYNNEOS vaccine in anyone with:
      i. History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin.
      ii. History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products.
      iii. Moderate or severe acute illness with or without fever.

      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.

   c. **Defer** vaccination in persons previously diagnosed with mpox because mpox infection likely confers immune protection.
      i. Immunocompromised persons diagnosed with mpox virus infection after their first dose of JYNNEOS vaccine may be eligible to receive the second

dose of JYNNEOS based on the clinical judgement of the patient's clinical team.

3. **Assess Persons for Vaccine Dose and Route:**
   a. JYNNEOS vaccine can be administered subcutaneously or intradermally, however the standard regimen is to give it subcutaneously. The standard regimen is the FDA-approved dosing regimen.
   b. **Please note that this document addresses subcutaneous administration (standard regimen) only.**

4. **Provide information on the JYNNEOS vaccine and obtain consent:**
   a. Inform each patient or a patient's legal guardian, as applicable, of the risks, benefits, and alternatives of receiving the JYNNEOS vaccine.
   b. As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the Vaccine Information Statement for JYNNEOS-and provide a copy of the "Vaccine Information Statement or direct the individual to: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf
   c. For the Spanish version of the Vaccine Information Statement, use this link: https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf
   d. Obtain consent to administer the vaccine from the patient or the patient's legal guardian, as applicable. [Insert how the Organization will be documenting consent and what forms will be used].

5. **Storage and Handling of Vaccine:**
   - For storage and handling details of JYNNEOS vaccine please refer to the package insert: https://www.fda.gov/media/131078/download?attachment

6. **Prepare to Administer Vaccine:**
   a. Allow JYNNEOS vaccine to thaw and reach room temperature before use. A frozen vial will take less than 10 minutes to thaw at room temperature.
   b. When thawed, JYNNEOS is a milky, light yellow to pale, white colored suspension.
      i. **Carefully inspect the vial prior to preparation:** Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.
   c. Swirl the vial gently for at least 30 seconds. Do not shake.
   d. Withdraw dose of 0.5 mL using a 23–25 gauge, 5/8" needle into a sterile syringe for injection.

7. **Administer Vaccine:**
   Visually inspect each dose in the dosing syringe prior to administration.
   a. Verify the final dosing volume of 0.5 mL.

b. 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.

8. **Document Vaccination**
Document each patient's vaccine administration information, route of administration, and follow-up in the following places:

Medical Record System: Ensure that the patient's name, the date the vaccine was administered, the name of the vaccine, the manufacturer and lot number, the vaccination site and route, address of administering site, and the name and title of the authorized person administering the vaccine, and the date it was given to the patient is documented in the patient's medical record or on a separate form retained by the authorized vaccinator who has administered the immunization, and in a retrievable format available to the State Education Department and the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, refusal). Documentation must be completed within 24 hours of administration. This information, whether in a medical record or separately kept, must be recorded and maintained in accordance with 8 NYCRR § 29.2(a)(3).

Signed Certificate of Immunization (given to the patient)**:** Record the patient's name, date of vaccination, name/location of the administering clinic, administering vaccinator, name of vaccine, manufacturer and lot number, and recommendations for future immunizations.

New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR): Report all doses administered to those 18 years of age and younger to NYSIIS or CIR within 14 days of administration. Report all doses administered to those 19 years of age and older to NYSIIS and CIR after obtaining consent. With respect to NYSIIS, if the dose was documented in the Countermeasure Data Management System (CDMS), then the NYSDOH must transmit data from CDMS to NYSIIS for all patients ages 18 and younger and for those who are 19 and older, with consent.

9. **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, or chicken or egg protein (AND who are currently avoiding exposure to all chicken or egg products).
- **15 minutes**: Can consider for all other persons.

10. **Be prepared to Manage Medical Emergencies:**
Be prepared for management of a medical emergency related to the administration of vaccine by maintaining written copies of the standing orders and protocols for administration of epinephrine and diphenhydramine. Vaccinator must be responsible for

having emergency anaphylaxis treatment agents, related syringes and needles at the immunization site, including sufficient epinephrine to administer at least three (3) doses to persons of any weight, H1 antihistamine, blood pressure cuff, and a stethoscope and timing device to assess pulse. To prevent syncope, vaccinate patients while they are seated or lying down and assess for signs of syncope such as extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness or visual disturbances.

For more information, please see:

- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf.
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting" at https://www.immunize.org/catg.d/p3082a.pdf.

11. **Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS):**
    a. Report any vaccine adverse events or administration errors to the US Department of Health and Human Services. Visit https://vaers.hhs.gov/ to file a report or call 1-800-822-7967.
    b. Conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.
        - Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. To the extent feasible, also report suspected adverse reactions to the vaccine manufacturer by contacting Bavarian Nordic at toll-free phone 1-800-675-9596.

Order: I am hereby prescribing this non-patient-specific order for administration of mpox vaccine (JYNNEOS). Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may administer JYNNEOS vaccine as approved by the Food and Drug Administration, state and federal laws, Executive Orders, ACIP recommendations, Emergency Use Authorization, PREP Act Declaration for Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses, and the CDC's and New York State's Vaccination Program.

This non-patient specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on 9/5/2024 through 9/5/2025. In the event that I discontinue this non-patient-specific order prior to 9/5/2025, notice of such discontinuance shall be provided to those employees, volunteers, and contractors of the pharmacy licensed in New York State permitted to execute under this Order using the usual methods of communication.

Signature: _____ MD Date: 9/5/2024

Name of Physician: James V. McDonald MD, MPH

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: 9/5/2024

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