NEW YORK STATE | Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

Non-Patient Specific Standing Order for the Administration of the JYNNEOS vaccine via Subcutaneous Administration for Persons Aged 18 and Older by Pharmacists (Updated 09/5/2025)

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 standing orders in New York State (NYS) and who are certified in cardio-pulmonary resuscitation may administer the JYNNEOS Vaccine to eligible individuals, as permitted by its Biologics License Application (BLA) approval or Emergency Use Authorization (if applicable) by the U.S. Food and Drug Administration (FDA), state and federal laws, Executive Orders, Public Health Readiness and Emergency Preparedness (PREP) Act Declaration for Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses, COVID-19 PREP Act declarations, or the recommendations of the Advisory Committee on Immunization Practices (ACIP).

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 for acquiring mpox[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:
        - A new diagnosis of ≥1 sexually transmitted disease,
        - More than one sex partner,
        - Sex at a commercial sex venue, and/or

[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).

        - 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.
    - Travelers to countries with ongoing outbreaks. The Center for Disease Control and Prevention has determined that ongoing human-to-human transmission of clade I mpox virus in Central and East Africa[4] meets the criteria to be considered an outbreak and is issuing recommendations for vaccine use among travelers at increased risk of mpox exposure who are planning to travel to those specific countries.
        - Travelers to affected countries who anticipate the following activities should be offered vaccination with the 2-dose JYNNEOS series: sex with a new partner; sex at a commercial sex venue (e.g., sex club or bathhouse); sex in exchange for money, good, drugs, or other trade; or sex in association with a large public event (e.g., rave, party, or festival).

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.

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 or more 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:

[4] **As of August 6, 2025,** countries with sustained clade I mpox transmission include Burundi, Central African Republic, Democratic Republic of the Congo, Ethiopia, Kenya, Malawi, Mozambique, Republic of the Congo, Rwanda, South Sudan, Tanzania, Uganda, and Zambia. Countries with new clade II outbreaks include Liberia and Sierra Leone.

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.

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/current-vis/smallpox-monkeypox.html
   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, following the pharmacy's policies for consent.
   e. Provide written instructions to the vaccine recipient or the legal guardian of the vaccine recipient regarding appropriate course of action in the event of adverse reactions.
5. Prepare to Administer Vaccine:
   a. JYNNEOS is supplied in two presentations: The one-vial presentation contains JYNNEOS in a single vial with a yellow cap and does not require reconstitution before use. The two-vial presentation includes a vial with a yellow cap containing Lyophilized Antigen Component and a vial with a blue cap containing diluent component. The Lyophilized Antigen Component must be reconstituted with the diluent component to form JYNNEOS prior to administration.
   b. 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.
   c. 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 New York State Department of Health (NYSDOH) if the vaccine is discolored or contains particulate matter.

d. For the two-vial presentation, follow instructions on the package insert for reconstitution. Then withdraw a dose of 0,5 mL using a 23-25 gauge, 5/8 inch needle into a sterile syringe for injection.
e. For one-vial presentation. swirl the vial gently for at least 30 seconds. Do not shake.
f. Withdraw dose of 0.5 mL using a 23–25 gauge, 5/8 inch needle into a sterile syringe for injection.

6. Administer Vaccine:
   a. Visually inspect each dose in the dosing syringe prior to administration.
      i. Verify the final dosing volume of 0.5 mL.
      ii. 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.
7. Observe Patients after Vaccination:
   Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope for 15 minutes.
8. Document Vaccination
   Document each patient's vaccine administration information and follow-up in the following places:

   Medical Record System (including Countermeasure Data Management System [CDMS], as applicable) : 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 pharmacist, 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 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. Management of 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. Pharmacists shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles at the immunization site, including sufficient epinephrine to administer at least 3 prefilled syringes or autoinjectors, 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/imz-best-practices/preventing-managing-adverse-reactions.html
   - 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.
10. Reporting of adverse events
    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.
11. **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 and https://www.fda.gov/media/186359/download?attachment

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 a pharmacy licensed in New York State may administer mpox vaccine (JYNNEOS), as permitted as applicable by its Biologics License Application (BLA) approval or Emergency Use Authorization by the U.S. Food and Drug Administration (FDA), state and federal laws, Executive Orders, Public Health Readiness and Emergency Preparedness (PREP) Act Declaration for Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses, COVID-19 PREP Act declarations, or the recommendations of the Advisory Committee on Immunization Practices (ACIP).

This non-patient specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on September 5, 2025 through September 4, 2026. In the event that I discontinue this non-patient specific order prior to September 4, 2026, 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:  Date: September 5, 2025

Name of Physician: James V. McDonald, M.D., M.P.H

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383
Medicaid No:. 076963570

NPI: 1619966959

Effective Date of Order: September 5, 2025