



# Department of Health

KATHY HOCHUL  
Governor

MARY T. BASSETT, M.D., M.P.H.  
Commissioner

KRISTIN M. PROUD  
Acting Executive Deputy Commissioner

## Guidance for Health Care Providers and Vaccine Administrators Monkeypox JYNNEOS Vaccination Information

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## Summary of Recent Changes

- Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is part of the orthopoxviral family, the same family of viruses that causes smallpox. Monkeypox symptoms are like smallpox symptoms, but milder, and the current clade of monkeypox is rarely fatal.
- On July 28, Commissioner Bassett declared the monkeypox outbreak an imminent threat to public health.
- On July 29, Governor Hochul signed Executive Order No. 20 declaring monkeypox a disaster emergency in the State of New York: <https://www.governor.ny.gov/executive-order/no-20-declaring-disaster-state-new-york>.
- Executive Order No. 20 suspends the requirement that health care providers who administer monkeypox vaccines to persons 19 years of age or older obtain consent of the vaccinees to report such vaccination to New York State Immunization Information System (NYSIIS) or the New York City Immunization Registry (CIR).
- Executive Order No. 20 also requires providers to report all monkeypox vaccinations for any individual to be reported to NYSIIS and CIR within 72 hours of administration.
- Centers for Disease Control and Prevention (CDC) issued changes to the JYNNEOS vaccine clinical considerations effective July 28, 2022: [Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC](#).
- Vaccination against monkeypox remains an important public health strategy for protecting public health.

## Key Points Regarding Monkeypox Vaccine and Patient Eligibility

There are currently two vaccines available to help protect against *orthopoxvirus infection*, including *monkeypox* and *smallpox*: JYNNEOS and ACAM2000. **New York State is not pursuing the deployment nor use of the ACAM2000 vaccine currently.** ACAM2000 is a live, attenuated, replication-competent vaccine indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

CDC-held Emergency Access (EA) Investigational New Drug (IND) Protocol allows use of ACAM2000 for non-variola orthopoxvirus Infection (e.g., monkeypox) during an outbreak. Information on how to submit an EA-IND application can be found here: [IND Applications for Clinical Treatment \(Expanded Access\): Overview | FDA](#).

The CDC recommends that JYNNEOS is used as a preferred option to ACAM2000 for primary *orthopoxvirus* vaccination and booster doses, in addition to use as pre-exposure prophylaxis against *orthopoxviral* infection among persons at risk for such exposures.

The effectiveness of the JYNNEOS vaccine against the virus circulating in the current 2022 outbreak is unknown currently. To better understand the protective benefits of this vaccine during the current outbreak, data will be collected to help define JYNNEOS vaccine efficacy. The immune response takes 14 days after the second dose for maximal development.

## JYNNEOS (also known as IMVAMUNE, IMVANEX, MVA) Vaccine Use and Availability

JYNNEOS is a live, attenuated, non-replicating vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus:

- Licensed by FDA in September 2019.
- JYNNEOS is indicated 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.
- Statewide eligibility will be posted and updated here:  
<https://health.ny.gov/diseases/communicable/zoonoses/monkeypox/vaccine.htm>.

Currently, CDC is working with states to deploy the US Food and Drug Administration (FDA)-approved JYNNEOS vaccine that can be used as either pre-exposure prophylaxis (PrEP) or standard post-exposure prophylaxis (PEP) for monkeypox or post-exposure prophylaxis (PEP)++

There is currently a limited federal supply of JYNNEOS vaccine, although more vaccine is expected in the coming weeks and months. The New York State Department of Health (NYSDOH) is distributing vaccine in a phased approach, as it becomes available to states, in accordance with CDC guidance.

- Phase 1 (July 11 through about July 15) offers a limited number of vaccine doses and is focused on reaching those at high risk of a recent (within the past 14 days) exposure to monkeypox.
  - According to CDC, those at high risk of a recent exposure to monkeypox may include, but is not limited to, members of the gay, bisexual, transgender, and gender non-conforming community and other communities of men who have sex with men who have engaged (in the past 14 days) in intimate or skin-to-skin contact with others in areas where monkeypox is spreading.
    - This includes those who have had skin-to-skin contact with someone in a social network experiencing monkeypox activity, including men who have sex with men who meet partners through an online website, digital application (“app”), or social event (e.g., a bar or party).
- Phase 2 (after July 15 and through July 28) offers a modestly expanded supply of vaccine and also focuses on those at high risk of a recent exposure (within the past 14 days), where vaccination can reduce risk of infection and decrease symptoms if infection has occurred.
- Phase 3 (August 1 through about August 31) continues the targeted approach to vaccine distribution and also provides vaccine for second doses to those who were vaccinated in the earlier phases. JYNNEOS vaccine continues to be in short supply.
- NOTE: People with a known exposure to a suspected or confirmed monkeypox case in the past 14 days should work directly with their local health department (LHD) and health care provider to discuss obtaining the JYNNEOS vaccine as quickly as possible. Please check the website for availability: <https://health.ny.gov/diseases/communicable/zoonoses/monkeypox/vaccine.htm>.

## Special Considerations for Individuals Receiving Orthopoxvirus Vaccine

### JYNNEOS Vaccine:

- JYNNEOS is FDA-approved for the prevention of smallpox and monkeypox in adults 18 years of age and older.
- In the United States and New York, there is currently a limited supply of JYNNEOS vaccine, though more is expected in the weeks and months ahead. New York State is committed to an

equitable distribution of vaccine, and eligibility is currently focused on individuals with known or likely exposure in areas with the highest number of cases.

- Based on CDC guidance, and in working with local public health authorities including the New York City Department of Health and Mental Hygiene (NYCDOHMH), Statewide eligibility currently includes the following New Yorkers:
  - Individuals with recent exposure to a suspected or confirmed monkeypox case within the past 14 days.
  - Those at high risk of a recent exposure to monkeypox, including gay men and members of the bisexual, transgender, and gender non-conforming community and other communities of men who have sex with men and who have engaged in intimate or skin-to-skin contact with others in the past 14 days areas where monkeypox is spreading.
  - Individuals who have had skin-to-skin contact with someone in a social network experiencing monkeypox activity, including men who have sex with men who meet partners through an online website, digital application ("app"), or social event, such as a bar or party.
- CDC recommends that the vaccine be given within 4 days from the date of exposure in order 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 may not prevent the disease.

#### **Special Considerations:**

- Case by case situations can be considered for vaccine post 14 days after exposure but generally, vaccination after the onset of signs or symptoms is not expected to provide benefit
- A person who is diagnosed with monkeypox virus infection after their first dose of JYNNEOS is not recommended to receive the second dose at this time.
- A person who would be eligible for vaccination but has been diagnosed with monkeypox virus infection during this outbreak, which started in the United States on May 17, 2022, is not recommended to be vaccinated at this time.
- An immunocompromised person who is diagnosed with monkeypox virus infection after their first dose of JYNNEOS may be eligible to receive the second dose of JYNNEOS on a case-by-case shared decision-making basis based on the clinical judgment of the healthcare provider
- Individual-directed PEP or PEP++: based on supply, vaccine may be offered to people with certain risk factors without documented exposure to someone with confirmed monkeypox
- Pre-Exposure Prophylaxis or PrEP: person at risk for occupational exposure such as laboratory workers
- A person is considered up to date 2 weeks after second dose of JYNNEOS.
  - 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 (ACIP) — United States, 2022 | MMWR (cdc.gov)
- Currently, in people under age 18, a single patient emergency use authorization from the FDA is required using the CDC's expanded access investigational new drug protocol <https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-treatment-expanded-access-overview> please refer to CDC's [Clinical Considerations for Monkeypox in Children and Adolescents](#).

## Scheduling the Second Dose of JYNNEOS Vaccine

- JYNNEOS vaccine is an FDA approved two-dose vaccine, administered 28 days apart. Circumstances may arise where individuals need to receive their second dose at a different location than their first. Providers who have determined that the individual cannot return to the location where they received their first dose should either schedule a second dose for these individuals elsewhere or must supply information on how/where to obtain a second dose of vaccine. Please ensure all individuals are informed on how to locate second dose appointment.
- It is not recommended to give the second dose before the minimum interval of 28 days, but it can be given 4 days before the minimum interval of 28 days at 24 days. The second dose can be given 7 days (or 35 days after the first dose), but if there is a delay in administering the second dose, give the second dose as soon as possible and do not restart the series.

## Vaccine Safety

- Contraindications for JYNNEOS include severe or immediate reaction to any component of the vaccine (e.g., gentamicin, ciprofloxacin, egg protein, benzonase). The risk for a severe allergic reaction should be weighed against the risk for disease due to monkeypox. For complete information, please read the package insert or clinical considerations and the ACIP recommendations. Because of the documented risk for myocarditis after receipt of both ACAM2000 and mRNA COVID-19 vaccines and the unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving an mRNA COVID-19 vaccine or Novavax vaccine, particularly adolescent or young adult males. However, if an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an outbreak, administration of orthopoxvirus vaccine should not be delayed because of recent receipt of an mRNA COVID-19 vaccine. No minimum interval between mRNA COVID-19 vaccination and orthopoxvirus vaccination is necessary.
- There is insufficient human data on JYNNEOS in pregnancy. Studies in animals show no evidence of harm to the developing fetus.
- JYNNEOS safety and efficacy has not been evaluated in people who are breastfeeding or in young children.
- The risks and benefits of JYNNEOS should be discussed to determine if vaccine can be offered to pregnant or breastfeeding people who are otherwise eligible. Please see <https://www.cdc.gov/poxvirus/monkeypox/clinicians/pregnancy.html>.
- You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at [info@VAERS.org](mailto:info@VAERS.org) or by calling 1-800-822-7967.

### Prior to vaccine administration:

- Administer JYNNEOS **subcutaneously** into the fatty tissue over the triceps area in the upper arm.
- Inform each patient of the risks, benefits, and alternatives of receiving the JYNNEOS vaccine.
  - As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the Vaccine Information Statement prior to the individual receiving vaccine.
- Provide each patient a copy of the JYNNEOS Vaccine Information Statement (VIS) or direct the individual to <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf> to obtain VIS. The VIS is also available in Spanish: [https://www.immunize.org/vis/pdf/spanish\\_smallpox\\_monkeypox.pdf](https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf).

Proof of age should be requested but is not required. Documentary proof may include (but is not limited to):

- Driver's license or non-driver ID
- Military ID or Student ID containing a date of birth
- Birth certificate issued by a state or local government
- Consulate ID
- Current US passport or valid foreign passport
- Permanent resident card
- Certificate of Naturalization or Citizenship
- Life insurance policy with birthdate
- Parent/guardian attestation

### **Vaccine Reporting**

- On July 29, Governor Hochul signed Executive Order No. 20 declaring monkeypox a disaster emergency in the State of New York: <https://www.governor.ny.gov/executive-order/no-20-declaring-disaster-state-new-york>.
- Executive Order No. 20 suspends the requirement that health care providers who administer monkeypox vaccines to persons 19 years of age or older obtain consent of the vaccinees to report such vaccination to New York State Immunization Information System (NYSIIS) or the New York City Immunization Registry (CIR).
- Executive Order No. 20 also requires providers to report all monkeypox vaccinations for any individual to be reported to NYSIIS and CIR within 72 hours of administration.

### **Administration of Vaccine**

#### **JYNNEOS:**

- Is administered as a subcutaneous (SQ) injection. Allow the vaccine to thaw and reach room temperature before use. A frozen vial will take less than 10 minutes to thaw at room temperature.
- ACIP recommendations are here: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm>.

### **Vaccine Management**

#### **Ordering Instructions:**

- Monkeypox vaccines are currently only available through the Strategic National Stockpile (SNS).
- Requests for vaccine from the SNS will be made by NYSDOH or NYCDOHMH according to CDC defined allocation and distribution protocols.
- NYSDOH will provide vaccine through LHDs and their health care provider network and county partners.

#### **Storage and Handling Requirements:**

Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine, and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases.

Detailed information regarding vaccine storage and handling requirements is available at [CDC Vaccine Storage and Handling Toolkit](#). Additional details on JYNNEOS storage, transport, and temperature monitoring requirements can be found in Appendix A of this document.

#### **JYNNEOS Storage and Handling Requirements:**

1. [Package insert \(https://www.fda.gov/media/131078/download\)](https://www.fda.gov/media/131078/download). **Please note that the JYNNEOS manufacturer has provided a letter indicating expanded storage at refrigerated temperatures that is not indicated in the package insert.** This information can be found at <https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf>.
2. The vaccine comes in packages of 20 single dose vials.
3. Keep frozen at -25°C to -15°C (-13°F to +5°F) until expiration date.
4. DO NOT store on dry ice or below -50°C (-58°F).
5. Store in the original package to protect from light.
6. Do not re-freeze a vial once it has been thawed.
7. Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks.
  - a. Count 8 weeks from when the vial was first thawed and mark this “beyond use” date on the vial label. If the product expiration date on the carton is earlier, write that on the vial instead.
8. NEVER store vaccine in a “dormitory style” storage unit.

#### **Vaccine Expiration Dates:**

Determining when a vaccine expires is a critical step in proper storage and handling. The expiration date should always be checked prior to preparing or administering vaccine. Expired vaccine should NEVER be administered. As additional stability data become available, the expiration dates for some products may change.

Expiration date is printed on the vaccine carton, not individual vials. The expiration date can also be looked up at [Monkeypox \(hhs.gov\)](#).

#### **Temperature Monitoring Requirements:**

- You must use a digital data logger (DDL) to monitor the temperature of vaccines at all times during storage and transport.
- Record temperatures daily on a temperature log. Examples can be found at <https://www.immunize.org/handouts/temperature-logs.asp>.
- When positioning a DDL in a permanent vaccine storage unit, place the buffered probe in the center of the unit with the vaccines surrounding it, and attach the temperature display to the outside of the unit.
- When packing a DDL in a vaccine transport container:
  - Make sure the buffered probe has been conditioned in the refrigerator or freezer for at least 5 hours prior to transport.
  - Remember to reset the minimum/maximum temperature display.
  - Place buffered probe as close as possible to vaccines in the transport container.
  - Do not place buffered probe directly next to ice packs or other coolants.
  - Attach temperature display to the outer lid of the transport container whenever possible.
- Temperature excursions must be reported to the manufacturer to determine vaccine viability. DO NOT use vaccine that has experienced a temperature excursion until viability has been determined. Contact Bavarian Nordic at toll-free phone 1-800-675-9596. General questions on

temperature excursions can be sent to NYSDOH at [vaccinetempexcursion@health.ny.gov](mailto:vaccinetempexcursion@health.ny.gov) or to NYCDOHMH at [PQAUnit@health.nyc.gov](mailto:PQAUnit@health.nyc.gov).

#### **Inventory Management:**

- Doses, lot and expiration information must be manually entered as [inventory in NYSIIS](#) or CIR (<https://www1.nyc.gov/assets/doh/downloads/pdf/cir/covid-19-transfer-vim-guide.pdf>) upon receipt. This must be done manually since orders are not managed in these systems.
- Providers must choose the eligibility category of '317' to have doses administered to patients automatically deduct from inventory in NYSIIS/CIR.
- Providers must track any doses wasted by lot number and reason (temperature too cold/hot, dropped vial, expired) and report this information to NYSDOH and/or NYCDOHMH as requested.

#### **Vaccine Redistribution:**

- When redistributing vaccine to other providers, [standard transportation guidance](#) must be followed. Ensure continued temperature monitoring via digital data loggers.
  - Complete the appropriate transport tracking sheet, including temperatures during transport, found in this guidance. Providers must complete the tracking sheets and maintain for your records for a minimum of 3 years.
- The releasing provider must track date and time of redistribution, receiving provider info, lot number, expiration date, and number of doses redistributed. This information must be supplied to NYSDOH and/or NYCDOHMH upon request for vaccine accountability.
- Receiving and sending providers must maintain accurate inventory in NYSIIS or CIR for improved tracking.

#### **Resources for JYNNEOS**

- [MMWR for JYNNEOS](#)
- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions," at and <https://www.cdc.gov/vaccines/vpd/smallpox/>
- CDC COCA call: [https://emergency.cdc.gov/coca/calls/2022/callinfo\\_062922.asp](https://emergency.cdc.gov/coca/calls/2022/callinfo_062922.asp)
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at <https://www.immunize.org/catg.d/p3082.pdf>
- BLA: <https://www.fda.gov/media/131870/download>
- Package Insert: <https://www.fda.gov/media/131078/download>
- FDA statement: <https://www.fda.gov/vaccines-blood-biologics/jynneos>



**APPENDIX A**  
**New York State Vaccine Program**  
**Storage and Transport Guidance for JYNNEOS Vaccine**  
**JULY 2022**

**Store JYNNEOS Vaccine**

<p><b>Frozen</b> -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> <li>• <b>Store frozen until expiration date.</b></li> <li>• NEVER REFREEZE THAWED VACCINE.</li> </ul>	<p><b>OR</b></p>	<p><b>Refrigerated</b> 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> <li>• <b>Store refrigerated for up to 8 weeks.</b></li> <li>• Count 8 weeks from the date vaccine was <i>first</i> placed in refrigerated storage. Label vaccine vial/carton with this 8-week “beyond use” date.</li> <li>• Vaccine must be discarded after 8-week “beyond use” date <i>or</i> after expiration date, <i>whichever comes first</i>.</li> </ul>
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**ADDITIONAL CONSIDERATIONS:**

- Never store vaccine in a combination refrigerator/freezer or dorm-style unit. **For more information about acceptable vaccine storage units**, see page 8 of [CDC’s Vaccine Storage and Handling Toolkit](#).
- Protect vaccine from light. Keep vials in original packaging whenever possible.
- Expiration date is printed on vaccine carton (not individual vials) or can be looked up at [Monkeypox \(hhs.gov\)](#).
- Note that this storage and handling information differs from the package insert. The information on this document supersedes the package insert.

**Transport JYNNEOS Vaccine**

<p><b>Frozen</b> -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> <li>• Never use dry ice for frozen transport.</li> <li>• If using <a href="#">CDC’s water bottle transport system</a>, the water bottles must be frozen solid (not conditioned).</li> <li>• If vaccine begins to thaw in transit, store vaccine in a refrigerator at the receiving location. Never refreeze thawed vaccine.</li> </ul>	<p><b>OR</b></p>	<p><b>Refrigerated</b> 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> <li>• Count hours used for transport against maximum allowable refrigerated storage time.</li> <li>• If using <a href="#">CDC’s water bottle transport system</a>, the water bottles must be conditioned (not frozen solid).</li> </ul>
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**ADDITIONAL CONSIDERATIONS:**

- Never use soft-sided or collapsible food/beverage coolers for vaccine transport. **For more information about acceptable vaccine transport containers**, see pages 22-23 of [CDC’s Vaccine Storage and Handling Toolkit](#).
- To the extent possible, **avoid**: leaving the transport container in direct sunlight; leaving the transport container unattended; opening the transport container.
- If using a personal or company vehicle to transport vaccine, bring vehicle to a comfortable temperature before replacing transport container inside. Never place transport container in the trunk.
- Protect vaccine from drops, shocks, and vibration. Secure transport container in vehicle. If transporting individual vials or partial cartons, use dunnage (padding material such as bubble wrap) to hold vials in place within the transport container.
- Plan route to minimize transport time. In general, transport time or transport time plus clinic workday should be 8 hours maximum.
- **Every time vaccine is moved, the cold chain is put at risk. Therefore, limit transports to the extent possible.**

**Temperature Monitoring Requirements**

- You **must** use a digital data logger (DDL) to monitor the temperature of vaccines **at all times during storage and transport**.
- When positioning a DDL in a permanent vaccine storage unit, place the buffered probe in the center of the unit with

the vaccines surrounding it, and attach the temperature display to the outside of the unit.

- When packing a DDL in a vaccine transport container:
  - Make sure the buffered probe has been conditioned in the refrigerator or freezer for at least 5 hours prior to transport.
  - Remember to reset the minimum/maximum temperature display.
  - Place buffered probe as close as possible to vaccines in the transport container.
  - Do not place buffered probe directly next to ice packs or other coolants.
  - Attach temperature display to the outer lid of the transport container whenever possible.
- Most DDLs have a minimum/maximum temperature display. **If your DDL does not have a “min/max” display, you must check and record temperatures at more frequent intervals. See below.**
- If being transported for use at an off-site clinic or for redistribution, vaccine should be placed in a permanent storage unit immediately after arriving at the destination. **If holding vaccine in a transport container throughout the clinic day, you must check and record temperatures at more frequent intervals. See below.**

**SUMMARY TABLE: VACCINE TEMPERATURE MONITORING REQUIREMENTS**

Vaccine is stored in a:	DDL displays “min/max” temperature:	DDL does NOT display “min/max” temperature:
<b>Permanent storage unit on site at your location.</b>	Check DDL and record time and <b>min/max temperature</b> on paper log <b>1x each clinic day</b> (start of business).	Check DDL and record time and <b>current temperature</b> on paper log <b>at least 2x each clinic day</b> (start and end of business).
<b>Transport container traveling from one location to another.</b>	Check DDL and record time and <b>min/max temperature</b> at the beginning of transport <b>and</b> upon arrival at destination.	Check DDL and record time and <b>current temperature</b> at the beginning of transport <b>and</b> upon arrival at destination.
<b>Permanent storage unit during an off-site or satellite clinic.</b>	Check DDL and record time and <b>min/max temperature 1x</b> (when vaccine is moved from transport container to permanent storage unit).	Check DDL and record time and <b>current temperature at least 2x during clinic day</b> (when vaccine is moved from transport container to permanent storage unit <b>and</b> at end of clinic day).
<b>Transport container during an off-site or satellite clinic.</b>	Check DDL and record time and <b>min/max temperature whenever container is opened.</b>	Check DDL and record time and <b>current temperature at least 1x per hour.</b>
<b>Frequency of full DDL temperature data review/download</b>	Review DDL data at least <b>1x per week and anytime min or max is outside acceptable range.</b>	Review DDL data for temperature excursions at least <b>1x per day.</b>