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

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Summary of Recent Changes

- Statewide eligibility has now been expanded to include immunization of all individuals at risk of becoming infected with Monkeypox.
- Recommendation to use “no” or “low” dead space tuberculin needles/syringes to maximize the number of doses able to be drawn from the vial.

Key Points Regarding Monkeypox Vaccine

- Monkeypox is a 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.
- 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.
- Vaccination against monkeypox remains an important public health strategy for protecting public health.
- New York State’s response to the Monkeypox outbreak can be found at the [NYSDOH website](#).

JYNNEOS (also known as IMVAMUNE, IMVANEX, MVA) Vaccine Use, Eligibility 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*:

- JYNNEOS vaccine is US Food and Drug Administration (FDA)-approved (licensed) for the prevention of smallpox and monkeypox disease in adults 18 years of age and older via subcutaneous administration of two 0.5mL doses administered 28 days (4 weeks) apart (standard regimen).
- On August 9, 2022, an alternate regimen of [intra-dermal administration](#) of two 0.1mL doses was authorized [under an Emergency Use Authorization \(EUA\) to include individuals over 18 years of age](#) to maximize the availability of vaccine based on a [published study in the Vaccine journal](#).
- The following are the **exceptions** to the recommended two dose series:
 - JYNNEOS is only for prevention for people at risk due to exposure and not treatment. Persons with symptomatic infection should discuss medical treatments such

as TPOXX with their healthcare provider. If someone becomes symptomatic **between their 1st and 2nd JYNNEOS dose**, they should not receive the second dose.

- In contrast, an **immunocompromised person** who is diagnosed with monkeypox after their first dose of JYNNEOS may be eligible to receive the second dose on a case-by-case basis, using shared decision making, and clinical judgement of the healthcare provider. More information can be found within the [Vaccination Administration Considerations for Specific Populations](#) at the [CDC's Interim Clinical Considerations for the use of JYNNEOS](#).
- For intradermal administration training resources, please visit the New York State Department of Health (NYSDOH) website at [Monkeypox for Healthcare Providers \(ny.gov\)](#). The CDC has also provided multiple resources regarding [intradermal administration](#).

Currently, CDC is working with states to deploy 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 NYSDOH is distributing vaccine as it becomes available to states, in accordance with CDC guidance.

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 healthcare provider to discuss obtaining the JYNNEOS vaccine as quickly as possible.

Statewide eligibility has now been expanded to include all individuals at risk of becoming infected with Monkeypox. Exposure includes the following:

- Individuals with recent exposure to a suspected or confirmed monkeypox case within the past 14 days. (PEP)
- 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. (PEP++)
- 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. (PEP++)
- Any individual that may be at risk of future exposure to infection with monkeypox, even though they are not at high risk of a recent exposure to monkeypox. (PrEP)
- Statewide eligibility will be posted and updated at the [NYSDOH Monkeypox website](#).

Special Considerations for Individuals Receiving *Orthopoxvirus* JYNNEOS Vaccine

- The Centers for Disease Control and Prevention (CDC) recently issued changes to the JYNNEOS vaccine clinical considerations; [Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC](#).
- Based on this EUA expansion, there are several updates to [the vaccine schedule and dosing regimen](#) for the JYNNEOS vaccine.
- Currently, intradermal (ID) administration is recommended for persons 18 years and older who DO NOT have a history of keloid scars. Intradermal administration is NOT approved for individuals under the age of 18 years of age.

- Persons aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcutaneous regimen **may receive a second dose with the alternative intradermal regimen** at the recommended interval (i.e., 28 days) to complete the vaccination series. There are [exceptions](#) to the 2-dose primary series.
- A person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.
- For individuals younger than 18 years old, or people of any age who have a history of developing keloid scars, JYNNEOS should be administered by subcutaneous injection (standard regimen). For further information please see the [CDC clinical considerations for children and adolescents](#).
- CDC recommends that the vaccine be given within 4 days from the date of exposure 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.
- If the second dose is not administered during the recommended interval, it should be administered as soon as possible and there is no need to restart or add doses.
- JYNNEOS can be administered to people with immunocompromising conditions. A [summary of vaccination administration considerations](#) for specific populations by age and medical condition can be found within the CDC’s Interim Clinical Considerations for Orthopox Vaccines.
- Currently, there is no data on administering JYNNEOS at the same time as other vaccines. JYNNEOS typically may be administered without regard to timing of other vaccines. There are additional considerations if administering a COVID-19 vaccine. See [Interim Clinical Considerations for Coadministration](#).
- A person is considered up to date 2 weeks after second dose of JYNNEOS administered 28 days apart.
- Updates to the dosing regimen and vaccination schedule are summarized in [Table 2](#) within the CDC’s Interim Clinical Considerations for JYNNEOS.

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 up to 4 days before and 7 days after the minimum interval of 28 days (24-35 days). 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) should not receive this vaccine. For complete information, please read the [package insert](#) and the [ACIP recommendations](#).
- Precautions include a 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, persons with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination
- 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, 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.
- Vaccines inadvertently administered intramuscularly (IM) can be considered valid doses and do not need to be repeated. IM doses need to be reported to the manufacturer at drug.safety@bavarian-nordic.com
- Vaccines inadvertently administered with improper intradermal technique, (e.g., inadvertent subcutaneous administration of 0.1 mL when intradermal route was intended, i.e., no visible “wheal” was formed) may result in lower-than-authorized dose administered.
 - Repeat dose immediately via intended route (no minimum interval).
 - Repeated dose should be placed at least 2 inches away from the initially attempted site placement.
- Please see [Vaccine Administration Errors and Deviations](#) for further details.
- 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 or by calling 1-800-822-7967.
- VSafe will be added for monitoring in the future.

Consent for Vaccination of Minors

Entities operating vaccination sites may use the following verification methods as a model for securing consent for vaccination of minors, in consultation with counsel as needed. It is important to verify the age of any individual who appears to be a minor to ensure consent is obtained, confirm eligibility, and ensure the proper administration of the JYNNEOS vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor’s age. Documentary proof may include (but is not limited to):

- Driver’s license or non-driver ID
- 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

For all minors, a parent or legal guardian must provide consent for vaccination.

6 month–5-year-olds:

For minors who are 6 months through 5 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.

16 and 17-year-olds:

For minors 16 or 17 years of age, consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor.

Vaccine Reporting to NYSIIS or CIR: Executive Order No. 20

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 vaccinations 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 or CIR within 72 hours of administration.

Questions and issues regarding vaccine reporting to **NYSIIS** should be directed to nysiis@health.ny.gov

Administration of JYNNEOS Vaccine

Prior to JYNNEOS vaccine administration:

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 the website [here](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf) (<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf>) and VIS in Spanish [here](#). If given an intradermal or subcutaneous administration of JYNNEOS to individuals under the age of 18, the individual should receive the [EUA fact sheet](https://www.fda.gov/media/160773/download) (<https://www.fda.gov/media/160773/download>), also available in Spanish [here](#).

JYNNEOS Vaccine Administration:

- Yellow capped single-dose vial with turquoise and white label.
- Can be administered as a subcutaneous (Subcut) injection or intradermal (ID) 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 on the administration of the JYNNEOS vaccine can be found [here](#).
- Information regarding vaccine administration errors and deviations can be found [here](#).

- Contact information for manufacturer Email: medical.information_US@bavarian-nordic.com
U.S. phone number: 1-844-422-8274; U.S. fax number: 1-843-422-8274

Subcutaneous (Subcut) Administration (Standard Regimen)

- Allow JYNNEOS vaccine to thaw and reach room temperature before use and should be a milky, light yellow to pale white colored suspension
- Swirl the vial gently for at least 30 seconds
- Withdraw full dose of **0.5 mL** using a 23–25 gauge, 5/8” needle into a sterile syringe for injection
- For persons >12 months of age: 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
- For infants <12 months of age: Administer JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle.
- Preparation and administration of the standard dosing regimen:
<https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/guidance-jynneos-prep-admin-stand.pdf>

Intradermal (ID) Administration (Alternate Regimen)

- Allow JYNNEOS vaccine to thaw and reach room temperature before use, and should be milky, light yellow to pale white colored suspension
- Swirl the vial gently for at least 30 seconds
- Withdraw full dose of **0.1 mL** using 26 or 27 gauge, 1/4, 3/8, or 1/2” needle with a short bevel into a tuberculin syringe
 - The use of “no” or “low” dead space needles/syringes will ensure the most accurate measurement of 0.1 mL and maximize the number of doses able to be drawn from the vial.
 - If a full 5th dose cannot be drawn from the vial (e.g., less than 0.1 mL) DO NOT combine vaccine from multiple vials to create a full dose. Infection control and safe injection practices should always be followed.
- Select and cleanse vaccination site 2-4 inches below the antecubital fossa (elbow) on the volar (inner) surface of the forearm
 - The preferred location for intradermal administration is the forearm. However, alternate sites based on patient preference including the upper back under shoulder blade (scapula), and upper chest could be considered
- While pulling the skin taut, position the needle bevel facing up and insert the needle at a 5-to 15-degree angle into the dermis
- Slowly inject 0.1mL intradermally producing a noticeable pale elevation of the skin (wheal or bleb)
- A bandage may be placed over the injection site as needed
- A person who presents for their second JYNNEOS vaccine dose who is still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) may have the second dose administered intradermally in the contralateral forearm or alternate site (Sites of Intradermal injection And Complications (medilgobiohealth.com))
- Resources to assist in intradermal (ID) administration have been provided by the CDC in [video](#) and [photograph](#) formats
- The CDC has provided resources regarding preparation and administration of the alternative dosing regimen [here](#)

- Interim recommendations [for vaccine administration errors and deviations](#) for Intradermal administration can be found at the CDC's Clinical Considerations for JYNNEOS

Post Vaccine Waiting Time

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
 - **30 minutes:** individuals 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 individuals

Vaccine Management

All providers must adhere to all requirements outlined in the [HHS Monkeypox Vaccination Program Provider Agreement](#). Providers located outside NYC must sign and return a NYSDOH Outbreak Vaccine Provider Agreement for JYNNEOS vaccine.

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.

General 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. Storage and handling summary specific to JYNNEOS can be accessed [here](#).

JYNNEOS Storage and Handling Requirements

- [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>.
- The vaccine comes in packages of 20 vials.
- Keep frozen at -25°C to -15°C (-13°F to +5°F) until expiration date.
- DO NOT store on dry ice or below -50°C (-58°F).
- Store in the original package to protect from light.
- Do not refreeze a vial once it has been thawed.
- Once thawed unpunctured vials may be kept refrigerated at +2°C to +8°C (+36°F to +46°F) for 8 weeks.

- 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.
- Unpunctured vials may be stored at room temperature between 8°C and 25°C (46°F and 77°F) for up to 6 cumulative hours.
- After first puncture, vials can be stored at +2°C to +8°C (+36°F to +46°F) for up to 8 hours. Discard any remaining vaccine after 8 hours.
- 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 \(hhs.gov\)](https://www.hhs.gov/monkeypox/).

Temperature Monitoring Requirements

- You must use a digital data logger (DDL) to always monitor the temperature of vaccines 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 vaccinetempexcursion@health.ny.gov.

Inventory Management

- Doses, lot and expiration information must be manually entered as [inventory in NYSIIS](https://www1.nyc.gov/assets/doh/downloads/pdf/cir/covid-19-transfer-vim-guide.pdf) 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.
- Effective August 29, 2022, providers should count inventory as each vial of vaccine equal to 5 doses (i.e., receipt of 100 vials would be entered as 500 doses in NYSIIS/CIR).
- 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 vaccine doses that are unused, spoiled, damaged, or expired as wastage in the IIS.
- Inventory must be verified in NYSIIS/CIR by COB each Monday.

Vaccine Redistribution

- Vaccine should not be redistributed outside of the county without NYSDOH approval or outside of NYC without NYCDOHMH approval.
- 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 and maintain for your records.
- The releasing provider must track date and time of redistribution, receiving provider info, lot number, expiration date, and number of doses redistributed.
- Receiving and sending providers are required to update their active inventory in NYSIIS or CIR for improved tracking.

Resources for JYNNEOS

- [CDC Interim Clinical Considerations for JYNNEOS](#)
- [JYNNEOS Emergency Use Authorization for caregivers](#)
- [JYNNEOS Emergency Use Authorization for HCP](#)
- [CDC’s Vaccine Administration Resource Library](#)
- [Subcutaneous Injection Administration Video](#)
- [JYNNEOS Subcutaneous Vaccine Preparation and Administration Summary: see Related Resources](#)
- [CDC’s General Best Practice Guidelines for Immunization, “Preventing and Managing Adverse Reactions](#)
- [Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting](#)
- [JYNNEOS Vaccine Package Insert](#)
- [MMWR for JYNNEOS](#)
- [CDC’s General Best Practice Guidelines for Immunization, “Preventing and Managing Adverse Reactions](#)
- [CDC COCA Call](#)
- [Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting](#)
- [BLA](#)
- [FDA Statement on JYNNEOS](#)

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

Store JYNNEOS Vaccine

<p>Frozen -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> • Store frozen until expiration date. • NEVER REFREEZE THAWED VACCINE. 	<p>OR</p>	<p>Refrigerated 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • Store refrigerated for up to 8 weeks. • Count 8 weeks from the date vaccine was first placed in refrigerated storage. Label vaccine vial/carton with this 8-week “beyond use” date. • Vaccine must be discarded after 8-week “beyond use” date or after expiration date, whichever comes first. • Punctured vials may be stored refrigerated for up to 8 hours.
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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>Frozen -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> • Never use dry ice for frozen transport. • If using CDC’s water bottle transport system, the water bottles must be frozen solid (not conditioned). • If vaccine begins to thaw in transit, store vaccine in a refrigerator at the receiving location. Never refreeze thawed vaccine. 	<p>OR</p>	<p>Refrigerated 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • Count hours used for transport against maximum allowable refrigerated storage time. • If using CDC’s water bottle transport system, the water bottles must be conditioned (not frozen solid).
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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 placing 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:
Permanent storage unit on site at your location.	Check DDL and record time and min/max temperature on paper log 1x each clinic day (start of business).	Check DDL and record time and current temperature on paper log at least 2x each clinic day (start and end of business).
Transport container traveling from one location to another.	Check DDL and record time and min/max temperature at the beginning of transport and upon arrival at destination.	Check DDL and record time and current temperature at the beginning of transport and upon arrival at destination.
Permanent storage unit during an off-site or satellite clinic.	Check DDL and record time and min/max temperature 1x (when vaccine is moved from transport container to permanent storage unit).	Check DDL and record time and current temperature at least 2x during clinic day (when vaccine is moved from transport container to permanent storage unit and at end of clinic day).
Transport container during an off-site or satellite clinic.	Check DDL and record time and min/max temperature whenever container is opened .	Check DDL and record time and current temperature at least 1x per hour .
Frequency of full DDL temperature data review/download	Review DDL data at least 1x per week and anytime min or max is outside acceptable range .	Review DDL data for temperature excursions at least 1x per day .