Department of Public Health

Connecticut Vaccine Program

Monkeypox Vaccine Provider Manual

Updated 9/26/2022

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

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Abbreviations and Definitions

ACIP – Advisory Committee on Immunization Practices

CDC – Centers for Disease Control and Prevention

CoVP – Covid Vaccine Program

CT DPH – Connecticut Department of Public Health

CT WiZ – CT WiZ is the Immunization Information System for the state of Connecticut

CVP – Connecticut Vaccine Program; the pediatric immunization program for Connecticut

DDL – Digital Data Logger

FDA – Food and Drug Administration

HL7 – Health Level 7; this refers to a set of standards used to transmit health data between systems

IIS – Immunization Information System

LHD – Local Health Department or District

PEP – Post-exposure prophylaxis

PEP++ - Expanded post-exposure prophylaxis

PPE – Personal protective equipment

PrEP – Pre-exposure prophylaxis

SNS – Strategic National Stockpile

TMD – Temperature Monitoring Device

UI – User Interface

VAERS – Vaccine Adverse Event Reporting System

VIS – Vaccine Information Statement

Monkeypox Outbreak Response

The United States is currently experiencing an outbreak of monkeypox. Please see the CDC monkeypox webpage for additional information and situational updates relating to the ongoing 2022 outbreak.

Vaccine Strategies to Prevent Monkeypox

Currently, two vaccines licensed by the U.S. Food and Drug Administration (FDA) are available for preventing monkeypox infection – JYNNEOS (also known as Imvamune or Imvanex) and ACAM2000. Currently, only the JYNNEOS vaccine is being distributed in Connecticut. There is a limited supply of JYNNEOS, although more is expected in coming weeks and months.

When properly administered before or after a recent exposure, vaccines can be effective tools at protecting people against monkeypox illness. The following vaccination strategies are being used in the United States.

Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)

For the current outbreak, this approach can be considered as "standard PEP" for monkeypox. People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus. It is important that states and other jurisdictions identify contacts of confirmed or probable monkeypox cases to offer vaccine for PEP and to monitor for any early signs of illness.

CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease. If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. PEP, coupled with self-isolation and other prevention measures, are important strategies for controlling outbreaks and preventing further transmission of monkeypox.

Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++

This expanded approach can be considered as "individual-directed PEP" for monkeypox; public health officials refer to it as "expanded PEP" or "PEP plus-plus" or "PEP++".

People with certain risk factors are more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox. PEP++ may help slow the spread of the disease in areas with large numbers of monkeypox cases—which would suggest a higher level of monkeypox virus transmission.

Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP)

This approach refers to administering vaccine to someone at high risk for monkeypox (for example, laboratory workers who handle specimens that might contain monkeypox virus). The Advisory Committee on Immunization Practices recommendations for PrEP can be found here.

At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.

Vaccine Response Priorities

CDC recommends vaccine response concentrate on PEP for known contacts of monkeypox cases. Per CDC recommendations, JYNNEOS doses should be prioritized for those people who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions). When there is sufficient vaccine to transition beyond PEP, jurisdictions can begin expanded PEP or PEP++ as outlined in the White House Outbreak Response announced June 28, 2022. Pre-exposure prophylaxis is currently only recommended for laboratorians performing orthopoxvirus testing. While JYNNEOS vaccine supplies remain limited, widespread implementation of pre-exposure prophylaxis (PrEP) is not feasible.

Emergency Use Authorization (Updated 8/12/2022)

On August 9, 2022 the FDA issued an Emergency Use Authorization allowing for an alternative dosing regimen using intradermal administration, which increases the JYNNEOS supply by up to five-fold.

Requirements for Participating in the Monkeypox Vaccination Response

Enrollment in a CT Vaccination Program

Providers who wish to receive monkeypox vaccines must be enrolled in either the COVID-19 Vaccination Program (CoVP) or the Adult Vaccination Program.

Guidance in this document does not replace the requirements on the established, signed provider agreement. For reference, the COVID-19 vaccine provider agreement can be found here.

Monkeypox Vaccination Program Provider Agreement (Updated 9/12/22)

Providers must follow the requirements in their currently signed provider agreements (CoVP or Adult) for monkeypox vaccination. Please review those agreements if you are not readily familiar with them. CDC has developed a Monkeypox Provider Agreement. Providers who receive, store, or administer monkeypox vaccine will need to comply with the provisions in that agreement.

Communications

CT DPH has created a monkeypox vaccine provider distribution list in Everbridge for mass communication of policy changes. These messages will be delivered by email to provider contacts identified through program enrollment. If there is a change in provider contact, CT DPH should be notified.

Acceptance of Non-Patients

For at least the initial phase of implementation, vaccinating providers are expected to administer vaccine to referred patients, even if they are not existing patients or do not regularly utilize services.

Reporting Vaccine Administration

Providers are expected to track vaccine inventory and report doses administered to CT WiZ. Doses must be reported to CT WiZ within 48 hours of administration.

- Training links and resources are provided in Appendix A.
- Providers who have already onboarded to report doses administered electronically via an HL7 connection can find information on monkeypox vaccine messaging here: https://www.cdc.gov/vaccines/programs/iis/code-sets.html.
- For those using the User Interface (UI), see below for vaccine selection information:

Vaccine	Brand Name and Packaging	NDC	Manufacturer	CVX	CT WiZ Drop Down Selection
Smallpox Monkeypox	JYNNEOS (Single Dose Vial)	50632-0001-02	Bavarian Nordic A/S	206	Smallpox Monkeypox

Operations and Implementation

Distribution of Vaccine

CT DPH will guide vaccine resources to areas of need based on the geographic burden of cases and identified contacts. Pre-determined allocations have been shipped to depot locations within the state for longer term storage to facilitate rapid response for PEP of identified contacts of known cases.

Selected community providers will receive a smaller initial allocation to allow for scheduling of vaccine appointments for referred contacts without delay. As the monkeypox response evolves, this method may change. Any changes in vaccine allocation procedures will be communicated with vaccinating providers.

Receiving Vaccine

The following apply to sites receiving a direct shipment of vaccine:

- Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive.
- Vaccines must always be immediately checked and stored properly upon arrival.
- Check Digital Data Logger (DDL) upon shipment to ensure cold chain was maintained.
- Check invoice against what is shipped.
- Check for precipitates and/or discoloration of vial (possible evidence of contamination).

Providers receiving shipments must have someone available to accept the shipment during the days and hours you have designated for deliveries under your established provider agreement, or as communicated to CT DPH for receipt of shipments from the Strategic National Stockpile (SNS). If the practice will be closed for any day or time other than what is listed on your provider profile, it is the responsibility of the provider to contact the Immunization Program to let us know. Delivery hours can also be updated in CT WiZ.

Monkeypox Vaccine Redistribution

Vaccine ordered from the SNS may only be distributed to a maximum of 5 locations per jurisdiction. For the first few phases of monkeypox vaccine distribution, CT DPH will rely heavily on redistribution of vaccine from identified depot locations to community vaccinators. CT DPH will match depots with community partners to form a redistribution network. Currently vaccine redistribution is only approved between hospital depot locations, their associated hubs, and approved community providers. Approved community providers should not redistribute vaccine to an unapproved location, even if it is in your provider network.

When redistributing vaccines, appropriate precautions should be taken. Vaccine should only be transported using appropriate packing materials that provide maximum protection refer to the Vaccine Storage for Transport document. Additional vaccine information is provided in the Provider Information and Resources section. Providers should document transfer of doses in CT WiZ. Those who are not able to complete a transfer of vaccine in CT WiZ should submit a paper transfer form. Please see the Connecticut Vaccine Transfer Form. This includes hospital depots who may need to move vaccine between locations within an existing network.

Requesting Additional Vaccine

Due to limited supply, a request for additional vaccine will be fulfilled based on available inventory.

Providers should make requests for additional doses via email to DPH.Monkeypox@ct.gov. Requests for doses should be based on the number of doses administered during the week, second dose appointments scheduled, and remaining supply on-hand. A request is not a guarantee of doses, CT DPH will make the final determination of how many doses to send to the community provider and will communicate the allotment to the provider.

Second Dose Considerations (Updated 7/27/2022)

JYNNEOS vaccine is a two-dose series, however, providers do not need to hold back second doses from current stock to ensure adequate supply. At this time, please make sure inventory is updated in CT WiZ and order vaccines as needed to support second doses.

Patient Eligibility (Updated 9/26/2022)

Patients who meet criteria stated below are eligible for JYNNEOS vaccine. Patients seeking PEP should be prioritized. A suggested script for screening eligibility is provided in Appendix E.

Patients should live in Connecticut. Persons stationed in Connecticut and resident students/trainees at colleges/universities/vocational programs in Connecticut are eligible. This can be confirmed at the time of appointment by requesting that the patient bring a valid photo ID, or a piece of mail addressed to them. Government issued identification is not a requirement. Patients seeking a second dose of vaccine in CT who received a first dose in another state may be vaccinated if they can show proof of receipt of the first dose.

1. **Patients eligible for PEP**

   Known contacts identified by public health via case investigation, contact tracing, and risk exposure assessments (this may include sexual partners, household contacts, and healthcare workers). Patient eligibility for PEP is based on the CDC criteria for exposure risk assessment and public health recommendations for individuals exposed to a patient with monkeypox. Patient information will be communicated to the vaccinating provider by CT DPH or a local health department or district (LHD).

2. **Non-PEP eligibility criteria:**

   Patients who:
   - Had a sexual partner in the past 6 months who was diagnosed with monkeypox; or
   - Had multiple sexual partners in the past 6 months in a jurisdiction (e.g., city/state/country) with known monkeypox; or
   - Have a current partner who has multiple sexual partners in a jurisdiction with known monkeypox; or
   - Anticipate having a new sexual partner or partners in the next 6 months in a jurisdiction with known monkeypox.

   If eligible, persons should especially consider getting vaccinated if they:
   - Have had recent intimate contact with a partner who is showing symptoms of monkeypox, such as a rash or sores; or
   - Had recent intimate contact with a partner met through an online application or social media platform (such as Grindr, Tinder, or Scruff), or at clubs, raves, sex parties, saunas or other large gatherings; or
   - Have a condition that may increase their risk for severe disease (HIV or another condition that weakens your immune system, history of atopic dermatitis or eczema).

NOTE: Persons who have already had monkeypox likely have some protection against another infection and are currently not eligible to be vaccinated.

Per the existing provider agreements, all monkeypox vaccine providers must administer monkeypox vaccine regardless of the vaccine recipient's ability to pay vaccine administration fees.

Referral of Contacts for PEP

For CT Cases

- CT DPH or LHD will receive case notifications and will identify contacts of cases during case interviews.

- CT DPH/LHD staff will reach out to the contacts to notify of the exposure and determine the risk level classification, per guidelines referenced above.
    - If contact meets criteria and wants PEP, CT DPH/LHD determines most convenient provider location from the approved provider list. CT DPH/LHD will convey provider information to the contact and instruct them to wait for provider to reach out to schedule an appointment.
- CT DPH/LHD will contact the vaccinating provider and give the name and contact details for the patient.
- Vaccinating provider calls contact to schedule vaccine appointment.
    - Provider is expected to schedule the second dose appointment before the patient leaves the office.

For Contacts of Non-CT Cases or Self-reported Exposure

- Community providers, hospitals, or members of the public can reach out to CT DPH/LHD to report an exposure to a monkeypox case and request PEP.
- CT DPH/LHD staff will reach out to the contact to determine the risk level classification, per guidelines referenced above.
    - CT DPH/LHD/Provider staff will then follow the remaining steps listed above as applicable.

Patient Screening and PPE

Patients should be screened for monkeypox symptoms upon arrival but prior to entering the facility. Providers can do this via phone, telehealth, or other method approved by the practice. Patients who are symptomatic should not be vaccinated and should instead be referred for monkeypox testing. If patients are not symptomatic, staff administering vaccines can use the same precautions and PPE they would to prevent transmission of COVID-19.

Minimizing Vaccine Wastage of Remaining Doses in Punctured Vials (Updated 8/16/2022)

The guiding principle is to use all available doses once a vial is punctured (for intradermal administration there should typically be 5 doses per vial, each 0.1ml). Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and **discarded within 8 hours of the first puncture**. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.1 mL, discard the vial. Do not pool excess vaccine from multiple vials.at the end of a clinic day

Reasonable effort to use all available doses should include:

- Proactive planning –Maintain a waitlist of individuals who can be called in at short notice at the end of a clinic day should there be leftover doses. The waitlist could also include individuals who have received first doses once they are in the window for second doses.
- Active management –Near the end of the clinic day, if it seems that there will not be enough individuals to receive vaccine to make full use of a vial, call individuals in from your waitlist.
- Active management –If there are not enough people to make use of an entire vial, consider deferring administration to the next day, asking these individuals to return the next day for their vaccine. This should only be considered for those seeking PEP++.

See "Additional Doses" training (Appendix A) to document wastage in CT WiZ, if needed.

Procedure for "No shows" (Updated 8/12/2022)

CT DPH and LHD will refer patients who have expressed willingness to be vaccinated. If a patient does not show up for their scheduled appointment, the provider should try to contact them and reschedule. If the patient does not respond to the outreach attempt, the referring entity should be notified for documentation purposes. If the referring entity is unknown, please contact CT DPH. CT DPH does not expect an administering provider to continue to reach out multiple times for a patient who does not present for their appointment.

Provider Information and Resources

Vaccine Administration (Updated 8/16/2022)

Available Product Information

Clinicians administering JYNNEOS vaccine should follow manufacturer instructions and the recommendations of CDC/ACIP. CDC has issued updated interim clinical guidance for JYNNEOS vaccine.

- JYNNEOS is a two-dose series administered a minimum of 28 days apart.
    - An intradermal dose is 0.1 ml. This route should be used for all individuals aged 18 and older and without a history of keloid scars (per FDA Emergency Use Authorization).
    - A subcutaneous dose is 0.5 ml. This route should be reserved for individuals under the age of 18 or individuals of any age with a history of keloid scars.
- Providers should contact CT DPH if there is an issue meeting the 28-day minimum interval.
    - It is ok for someone who received their 1st dose subcutaneously to get their 2nd dose intradermally.
    - Only subcutaneous administration is authorized for persons under age 18 years.
- The vaccine can be stored through labeled expiration in a freezer between -25°C and -15°C (-13°F and 5°F) and for up to 8 weeks at refrigerated temperatures (2°C to 8°C/36°F to 46°F).
    - Please note this refrigerated temperature data differs from the manufacturer's package insert. See Appendix B for a letter of support from the manufacturer.
- See the JYNNEOS fact table (Appendix C) for a one-page product reference.
- See the "Additional Doses" training (Appendix A) to document inventory adjustments in CT WiZ.
- See links below for preparation and administration of a subcutaneous and intradermal immunization.
    - Two-page reference for subcutaneous and intramuscular administration
    - One-page reference for subcutaneous and intramuscular administration
    - Video demonstration of subcutaneous administration
    - Dose, Route, Site and Needle Size reference diagram
    - "You Call the Shots" vaccine administration module
    - Detailed instructions for intradermal administration are available in the EUA Fact Sheet.
    - A video intradermal vaccination demo posted to YouTube.
    - Step-by-step graphics for intradermal administration
    - JYNNEOS Smallpox and Monkeypox Vaccine Intradermal Vaccine Preparation and Administration Summary: ALTERNATIVE DOSING REGIMEN (cdc.gov)
    - Vaccine administration errors and deviations
    - Vaccine administration considerations for specific populations

General Best Practices

The following are best practices when administering vaccine.

- Only prepare vaccines when you are ready to administer them.
- Always check the lot number and expiration date and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared as a matter of quality control and patient safety.
- When administering an FDA approved vaccine, providers must make a Vaccine Information Sheet (VIS) available to each vaccine recipient or legal guardian accompanying the recipient. The fact sheet may be made available as a hard copy or via a website URL. The VIS for monkeypox vaccine can be found here.

Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) is a program for vaccine safety, co-managed by the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Reports should be submitted online under the circumstances listed below.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors.

The VAERS table of Reportable Events and the list of contraindications are vaccine specific. Adverse events to vaccines should be reported electronically through VAERS.

Other reporting requirements specific to monkeypox vaccines may be put in place when they become available. The CDC is currently developing a V-Safe module for monkeypox vaccine recipient monitoring. Providers should promote the use of this module once it is available.

Storage and Handling Guidance

Vaccine providers are responsible for maintaining appropriate cold chain storage, monitoring, and handling from the time the vaccine arrives at the facility until it is administered. Providers are expected to adhere to the storage and handling requirements that were received upon enrollment. The CDC Vaccine Storage and Handling Toolkit outlines CDC recommendations for vaccine storage and handling.

In addition to the storage and handling toolkit, information on storage and handling requirements can be found in the CVP Blue Folder and CoVP Provider Manual.

Temperature Ranges

The below ranges are specifically for storage of JYNNEOS vaccine.

- Refrigerators should maintain temperatures between 2°C and 8°C (36°F and 46°F).
- Freezers should maintain temperatures between -25°C and -15°C (-13°F and +5°F).

Refrigerator or freezer thermostats should be set at the factory set or midpoint temperature, which will decrease the likelihood of temperature excursions. Consult your owner's manual for instructions on how to operate the thermostat.

Provider Responsibilities for Temperature Monitoring

- Document minimum/maximum temperature at least once a day [preferably twice a day]
    - Temperature logs are available on the DPH Immunizations webpage.
- Assess and record temperatures twice a day (AM/PM) (See log sheets below).
- Document name (or initials) of the person who assessed/and recorded these temperature readings, time, and date of each reading.

- Download DDL data report monthly to review temperatures and identify any trends that might require corrective action.

See below for details on temperature excursions.

Temperature Excursion

A temperature excursion refers to when a storage device goes out of the temperature range required for the storage of vaccine. If a storage unit experiences a temperature excursion:

1. Quarantine and label vaccines exposed to an excursion as “DO NOT USE”.
2. Place vaccines in a unit where they can be stored under proper conditions.
3. Contact the Immunization Program to report a temperature excursion (860-509-7929)
4. Contact the vaccine manufacturer to obtain documentation supporting the usability of the vaccine.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in the unit or temperatures in the unit are fluctuating between extreme highs or lows, the vaccine supply is at risk. Use your Emergency Vaccine Backup Plan Template to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced. This plan should be posted on or near vaccine storage unit or where it can be easily accessed in the event of an emergency.

Providers must document information about all excursions and what steps were taken to correct any issues on the Vaccine Storage Troubleshooting Record.

Appendix A (Updated 8/16/2022)

CT WiZ Resources

- CT WiZ User Account Information-this page contains all information on how to request and setup a user account. It also contains the different types of access clinic staff can request to CT WiZ.
- CT WiZ login page – the main login screen for CT WiZ.
- Searching for a Patient- how to search for a patient in CT WiZ.
- Reporting a duplicate patient-directions on how to report a duplicate patient in CT WiZ.
- Printing an Immunization record- step by step directions on how to print immunization records directly from CT WiZ.
- Updating Clinic information- how to update your clinics name, address, phone number, delivery hours, and staff. Staff must be listed in CT WiZ before requesting access. DPH refers to the staff listing in CT WiZ when approving user requests.
- Reports Manual- a document that contains information on reports available to your clinic in CT WiZ.
- Adding Inventory- since your inventory will be ordered through an outside ordering portal, all doses received will need to be added to your inventory on hand in CT WiZ.
- Additional Doses- If you need to change the number of doses that were able to be administered from a vial, please add the doses via an adjustment on the inventory on hand screen. Click Action-Adjustment next to the vaccine you would like to add additional doses. Also learn how to update dosage on patient records and document Monkeypox vaccine wastage.
- Help Desk- submit a help desk ticket with any questions. Staff monitor these tickets during regular business hours. **Please use the help desk if you have any issues logging in, or need your password reset.**

For clinics using CT WiZ through the User Interface/Direct Entry (no EHR):

- Patient Management Training Video
- Patient Management- numerous how to documents relating to patient management in CT WiZ.
- Inventory Management Training Video

For clinics using CT WiZ that have their EHR electronically reporting:

- EHR Patient Management Training Video
- EHR Inventory Management Training Video

For clinics who need to complete an enrollment:

- Enrollment webpage- this page contains resources on how to complete the enrollment in CT WiZ.

Appendix B

CDC/DDID/NCEZID/DPEI

14-Jun-2022

To whom it may concern,

For operational flexibility, drug product may be shipped either frozen at -20°C (-4°F) or refrigerated at 2-8°C (36 46°F) during an event depending on freezer capacity at the receiving site(s). Upon receipt the vaccine can be stored as follows:

If vaccine is shipped frozen at -20°C and requires storage before use, maintain:

- Frozen (-20°C), if freezer capacity is available,

OR

- Refrigerated (2-8°C). Do not refreeze.

If vaccine is shipped at 2-8°C and requires storage before use, maintain:

- Refrigerated at 2-8°C. Do not refreeze.

Unopened vials of drug product may be stored at 2-8°C up to 8 weeks from thawing. This information has been provided by the vaccine manufacturer based on available supportive stability data.

Please be aware that this differs from the storage and use by period of 12 hours once thawed that is found in the JYNNEOS package insert (Sections 2.2. Preparation and Administration and 16.2 Storage Conditions).

If stored frozen (-20°C), the vaccine should be used within the printed expiration date on the carton. Please note that the expiration date is not shown on the individual vial."

Best Regards,

Rehana Mukhtar
Snr. Director CMC Regulatory Affairs Bavarian Nordic A/S

Appendix C

JYNNEOS Vaccine Fact Sheet

Smallpox and Monkeypox Vaccines

Brand Name and Manufacturer	JYNNEOS™/Imvamune/Imvanex (Smallpox/Monkeypox Vaccine, Live, Non-replicating) Bavarian Nordic A/S
NDC	50632-001-02 (carton) and 50632- 001-01 (vial)
Indication(s) and Intended Population(s)	Indicated for prevention of smallpox or monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection
Usage for Pediatric Population	The safety and effectiveness of JYNNEOS have not been assessed in individuals less than 18 years of age. The FDA has granted an EUA for the emergency use of JYNNEOS for active immunization by subcutaneous injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox infection. This 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
Dosing Regimen or Schedule	2-dose vaccine series (full protection is anticipated 2 weeks following 2nd dose)
Minimum Intervals	28 days apart
Warning and Precautions	**Severe Allergic Reactions:** Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS. **Altered Immunocompetence:** Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.
Screening & Consent	No consent form required by CT DPH for persons 18 years of age and older. Organization policy may vary.
Post-Exposure Prophylaxis (PEP)	The sooner an exposed person gets the vaccine, the better. CDC recommends that vaccine be given within 4 days from date of exposure to prevent onset of disease. If given between 4–14 days after date of exposure, vaccination may reduce symptoms of disease, but may not prevent the disease.
Efficacy	The efficacy of JYNNEOS to prevent monkeypox is inferred from seroconversion and immunogenicity that is noninferior as compared with replicating orthopoxvirus vaccines.
Administration	Subcutaneous injection for individuals less than 18 years of age; intradermal injection for individuals 18 years of age and older; allow vaccine to thaw and reach room temperature before use (see package insert for instructions for vaccine preparation and administration)
Adverse Reactions	Injection site reactions such as pain, swelling, and redness
PPE	Standard for immunization
Reconstitution	Do not dilute
Dosing Volume	0.5 mL each dose – subcutaneous 0.1 mL each dose - intradermal
Packaging	(20) single-dose vials (see image); ancillary supplies are not provided with vaccine
Storage: Unpunctured Vials	Shipped at -20°C and requires cold chain management; store frozen at -25°C to -15°C (-13°F to +5°F) until expiration date on vial label (or lookup here) **or at 2-8°C for up to 8 weeks (this differs from the package insert – see Provider Letter)**
Storage: Punctured Vials	N/A
Use-by Limits	Once thawed, hold at +2°C to +8°C (+36°F to +46°F) for 12 hours; do not refreeze
ACIP Recommendations	https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm
Package Insert	https://www.fda.gov/media/131078/download
VIS	Distribute Vaccine Information Statement before vaccination
CPT Code	TBD
CVX Code	206

Appendix D (Updated 9/8/2022)

Product Resources

Alternative Dosing Regimen: JYNNEOS Smallpox and Monkeypox Vaccine Intradermal Vaccine Preparation and Administration Summary: ALTERNATIVE DOSING REGIMEN (cdc.gov)

Standard Regimen Standing Orders: https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/monkeypox-jynneos-standing-orders-stand.pdf

Alternative Regimen Standing Orders: https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/monkeypox-jynneos-standing-orders-alt-dose.pdf

Appendix E (Updated 9/26/2022)

Suggested script for screening monkeypox vaccine eligibility

1. **Are you a resident of Connecticut, including as a student or trainee, or are you stationed in CT?** Yes or No
   If no, not eligible. If yes, still potentially eligible, go to #2.

2. **Do you meet at least one of the following criteria?** Yes or No

   NOTE: Read all the following criteria at once. Do not ask patients to respond to a category before moving to the next. Once the patient is aware of all criteria, they may self-attest with a yes or no response. No additional verification is required.

   - Had a sexual partner in the past 6 months who was diagnosed with monkeypox;
   - Had multiple sexual partners in the past 6 months in a jurisdiction (e.g., city/state/country) with known monkeypox.
   - Have a current partner who has multiple sexual partners in a jurisdiction with known monkeypox.
   - Anticipate having a new sexual partner or partners in the next 6 months in a jurisdiction with known monkeypox.

   If yes to #1 and #2, eligible for vaccine. Make appointment. If no to #2, not eligible.

*[NOTE: while age 18 or older is not a criterion for eligibility, **if the person is under 18, they are only eligible for a subcutaneous regimen.**]*

Appendix F (Added 9/8/2022)

Additional JYNNEOS Mobile Clinic Guidance

For the intradermal administration of JYNNEOS in a licensed mobile clinic or other healthcare setting* (hospital, healthcare office, urgent care):

1) The JYNNEOS vaccine is a 0.5 ml single dose vial. There is no preservative in the vial. The vaccine was originally authorized to be administered 0.5 ml subcutaneously in 2 doses, 4 weeks apart.

2) The FDA and CDC have authorized alternative dosing for JYNNEOS, to be administered 0.1 ml intradermally in 2 doses, 4 weeks apart. *Note: patients with a history of keloids and pediatric patients should still receive subcutaneous administration.*
3) If using intradermal administration, the vial will contain multiple doses. The vial should be refrigerated in between administering doses. Care should be taken not to remove the foil from the rim of the vial to prevent loosening of the cap and loss of product. The vial must be used and discarded within 8 hours of first puncture.
4) Do not pre-draw syringes for vaccine administration. Doses must be drawn up immediately prior to administration.
5) Tuberculin syringes should be used for intradermal administration.
6) All other vaccination best practices apply.

*If the clinic is held in a non-healthcare setting and a designated medication preparation area can be established away from the vaccine administration area, follow the guidance above. If space limitations or other considerations prohibit the establishment of a designated vaccine preparation area, then follow the guidance below.

For the intradermal administration of JYNNEOS during a mobile clinic held outdoors or indoors but when a designated medication preparation area CANNOT be established away from the vaccine administration area:

1) The JYNNEOS vaccine is a 0.5 ml single dose vial. There is no preservative in the vial. The vaccine was originally authorized to be administered 0.5 ml subcutaneously in 2 doses, 4 weeks apart.
2) The FDA and CDC have authorized alternative dosing for JYNNEOS, to be administered 0.1 ml intradermally in 2 doses, 4 weeks apart. *Note: patients with a history of keloids and pediatric patients should still receive subcutaneous administration.*
3) If using intradermal administration for mobile clinics or non-healthcare settings, the vial will contain multiple doses. Care should be taken not to remove the foil from the rim of the vial to prevent loosening of the cap and loss of product.
4) The manufacturer, Bavarian Nordic, the FDA, and the CDC currently do not provide guidance for the use of JYNNEOS in a mobile or non-healthcare setting.
5) Since mobile clinics or non-healthcare settings typically do not have access to sterile environments to draw doses from the vials, the vaccine provider must ensure all best practices regarding sterility are followed.
    a. The DPH suggests working with a facility that has an appropriate medication preparation area (such as a sterile compounding room) to draw up the doses of vaccine in pre-filled syringes and store according to proper cold-chain technique. These syringes should be labeled at the time of preparation and used or discarded within 6 hours after removal from the original vial.
6) All other vaccination best practices apply.