



Monkeypox Vaccine Provider Update

8/23/22

Updated Eligibility Criteria

CT DPH recently updated the eligibility criteria for expanded monkeypox post-exposure prophylaxis (PEP++) to the following:

A Connecticut resident aged 18 or older and:

- Have had a sexual partner in the past 14 days was diagnosed with monkeypox; or
- Have multiple sexual partners in the past 14 days in a jurisdiction (e.g., city/state/country) with known monkeypox.

Special Population Recommendations

Providers should reach out to existing patients who are at increased risk for severe monkeypox infection to determine if they meet the eligibility criteria and recommend vaccination with JYNNEOS. Clinicians should consider the following:

- Reaching out to patients who are immunocompromised (e.g., HIV positive) and engaging in behaviors that would put them at increased risk for infection per PEP++ guidelines.
- Identifying and counseling patients who meet HIV PrEP criteria and may also be at increased risk for monkeypox infection about the availability of JYNNEOS.

Ordering and Inventory Reporting

Ordering cadence:

- Submit new orders for JYNNEOS vaccines on Thursdays by noon based on what you will need for the following week, starting this week (August 25).
- You may place orders on other days if you will run out of vaccine, but we ask that you try to follow this schedule when possible.

Inventory Reporting

- Providers should perform a manual count and update JYNNEOS vaccine inventory in CT WiZ each Thursday by the end of the business day. Your inventory must remain current and will be tied to how much vaccine you will receive in the future.
- Additional updates to inventory should be made when vaccine is received by transfer or shipment.
- Please report inventory in CT WiZ in doses (instead of vials). For now, assume you will obtain 5 doses per vial. We understand that it will not always be possible to extract 5 doses per vial, but for inventory purposes we (and CDC) will operate under this assumption.



JYNNEOS Product Updates

Emergency Use Authorization

The U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the JYNNEOS vaccine to allow:

- Healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection.
- Use of the vaccine in individuals younger than 18 years of age determined to be at high risk of monkeypox infection; in these individuals JYNNEOS is administered by subcutaneous injection.

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of [medical countermeasures](#) (MCMs) needed during public health emergencies.

Intradermal JYNNEOS Monkeypox Vaccine Fast Facts (FDA)

Making vaccine available to all at risk for monkeypox infection is a top USG priority.

- JYNNEOS can be safely given by either the subcutaneous or the intradermal route
- The immune responses are similar using the two different routes of administration
- Intradermal administration allows the broadest protection of the community right now

Low dead volume syringes and needles (27 gauge) should be used to maximize the number of doses obtained from each vial.

Dosing Regimens

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥ 18 years	ID	0.1 mL	2	28 days
Standard regimen				
<u>People age <18 years</u>	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

JYNNEOS Preparation – Alternative Regimen

Unpunctured vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks.

Punctured vials may be stored continuously in the refrigerator for up to 8 hours.

Unpunctured vials may be held at room temperature between 8°C and 25°C (46°F and 77°F) for up to 6 cumulative hours.

There is no data to support vaccine stability of punctured vials at room temperatures. Punctured vials should stay in the fridge between each dose.

General Information
 Vaccine: JYNNEOS Smallpox and Monkeypox vaccine
 Multi-dose vial: maximum of 5 doses
 Diluent: None
 Dosage: 0.1 mL

Age Indications
 Persons 18 years of age and older who do not have a history of keloid scars

Vaccination Schedule
 Administer two doses of JYNNEOS (0.1 mL each) 28 days apart
 • For more details on the dosing interval, refer to www.cdc.gov/covavirus/monkeypox/considerations-for-monkeypox-vaccination.html.

Administration
 Intradermal (ID) injection into the volar surface of the forearm
 • If the volar forearm is not an option (e.g., heavy scarring, bilateral amputation), the upper back below the scapula may be used.

Thawing Frozen Vaccine

- Frozen vaccine takes 10 minutes to thaw and must be thawed before using. Use vials in the refrigerator before removing more vials from the freezer. Once thawed, store in:
 - Refrigerator:** Between 2°C and 8°C (36°F and 46°F).
 - Unpunctured vials may be stored in the refrigerator for up to 8 weeks.
 - Punctured vials may be stored continuously in the refrigerator for up to 8 hours.
 - Room temperature:** Between 8°C and 25°C (46°F and 77°F).
 - Unpunctured vials may be held at room temperature for up to 6 cumulative hours.
 - There is no data to support vaccine stability of punctured vials at room temperatures. Punctured vials should stay in the fridge between each dose.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date (BUD) labels to track storage times.

STEP 2
 While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.

www.cdc.gov/monkeypox

STEP 3
 Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).

www.cdc.gov/monkeypox

Prepare and Administer the Vaccine

- Assess recipient status:
 - Screen for contraindications and precautions.
 - Review vaccination history.
 - Review medical considerations.
- Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves, and any time hands become soiled.
- Frozen vaccine must be thawed for 10 minutes before using.
- Check the expiration date and/or beyond-use date. Do not use expired vaccine, unless you were able to confirm stability of the vaccine by contacting the manufacturer.
- With the vial upright, gently swirl the vaccine for 30 seconds.
- Examine the vaccine. It should be a milky, light yellow to pale white colored suspension. Do not use if liquid contains other particulate matter or is discolored.
- Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.
- Choose the correct equipment for intradermal injection: attach either a 26 gauge or 27 gauge, 3/8", 1/4 to 1/2" needle with a short bevel to the syringe. **Always use a new, sterile needle and syringe for each injection.**
- Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

Minimizing Wastage

Reasonable effort should be made to use all available doses in a vial. This includes:

- 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++.

For intradermal administration there should typically be 5 doses per vial, each dose 0.1ml. Once the vial is punctured and a dose is withdrawn, it should be stored at +2°C to +8°C (+36°F to +46°F) between administration of doses 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 to create a full dose.

Interchangeability of Dosing Regimens

When necessary, a person 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. For example:

- A person who received only one dose of the standard regimen before the date of initial Emergency Use Authorization for the alternative regimen (August 9, 2022), may receive one dose with the alternative regimen to complete the series.
- A person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.

Similarly, when necessary, a person who received one JYNNEOS vaccine dose intradermally (alternative regimen) may receive the second dose using subcutaneously (standard regimen).

Patient Counseling

Pre-vaccination Counseling

Recipients should be informed of the risks and benefits of JYNNEOS prior to vaccination. Healthcare providers should ascertain the medical history of recipients to appropriately determine the route of vaccine administration. Recipients should be counseled about possible side effects from vaccination including injection site pain, redness, swelling, induration, itching, fatigue, headache, nausea, chills, and muscle aches, and be provided with a JYNNEOS vaccine information statement (VIS) or FDA JYNNEOS EUA Fact Sheet, as applicable. There have been reports of prolonged duration of induration or erythema following intradermal administration. Side effects are usually self-limiting.

Post-vaccination Counseling

Given the unknown effectiveness of vaccination in this outbreak, people who are vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.

Clinical studies have not detected an increased risk for myopericarditis in recipients of JYNNEOS. However, people with underlying heart disease or three or more major cardiac risk factors should be counseled about the theoretical risk for myopericarditis following vaccination with JYNNEOS given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccines such as ACAM2000.

[Table 6. Summary of Vaccination Administration Considerations for Specific Populations by Age and Medical Condition](#)

[Table 7. Interim recommendations for JYNNEOS vaccine administration errors and deviations](#)

[Precautions and Contraindications](#)

EUA Fact Sheet for Recipients:

- [English](#)
- [Spanish](#)
- Available on the FDA [EUA webpage](#) in: Simplified Chinese, Korean, Tagalog, Vietnamese

[EUA Fact Sheet for Providers](#)

[Subcutaneous Preparation \(Standard Regimen\)](#)

[Monkeypox Provider Agreement](#)

[Clinician FAQs](#)

Question and Answers

To ask a question, please raise your hand using the hand icon on your screen, type your question in the chat box or if you are on the phone press *6 to unmute yourself.

If you have additional questions after the meeting, please feel free to email them to DPH.Monkeypox@ct.gov.