Vaccine Storage and Handling Toolkit Addendum

for SNS-supplied Jynneos

JULY 2026

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Purpose and Background

This addendum to the Vaccine Storage and Handling Toolkit provides information, recommendations, and resources to assist providers with meeting the requirements of the Department of Health and Human Services (HHS) Monkeypox Vaccination Program Provider Agreement for storing and handling **Jynneos**, a monkeypox vaccine.

Two vaccines, Jynneos and ACAM2000, are licensed by the Food and Drug Administration (FDA) for the prevention of monkeypox. Jynneos was the primary vaccine deployed from the Strategic National Stockpile (SNS) during the domestic monkeypox outbreak response. **This addendum focuses on storage and handling guidance for HHS-supplied Jynneos from the SNS.** For clinical guidance on the use of Jynneos, please refer to CDC's Clinical Considerations for Monkeypox Vaccines website.

Provider Agreement Requirements

The HHS Monkeypox Vaccination Program Provider Agreement is expected to continue until all HHS-supplied Jynneos lots have been used or reach their expiration. Providers using HHS-supplied Jynneos vaccine received before August 30, 2024 (when HHS distribution ended) must follow the requirements in the Provider Agreement. Providers must be knowledgeable about and comply with the storage and handling guidance and best practices detailed in CDC's general *Vaccine Storage and Handling Toolkit*.

The Provider Agreement requires providers to

- Store and handle Jynneos under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers, manufacturer's vaccine package insert, and CDC's storage and handling guidance.
- Monitor storage unit temperatures at all times using equipment and practices that comply with CDC's vaccine storage and handling guidance.
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with vaccine expiration dates and beyond-use dates/times.
- Preserve all vaccine management records for at least three years, or longer if required by state, local, or territorial law.

Emergency Use Authorization (EUA)

On December 23, 2024, the FDA clarified that the authorized use of Jynneos under the Emergency Use Authorization (EUA) applies to both commercial and HHS-supplied lots of Jynneos. Additional information about the EUA can be found on the FDA's Emergency Use Authorization website.

Expiration Date Extension

On October 18, 2024, FDA approved an expiration date extension from October 31, 2024, to August 31, 2026, for **lots FDP00017, FDP00018, FDP00019,** and **FDP00020** when maintained at -25°C to -15°C. These are the only remaining Jynneos lots deployed from the SNS that have not reached their expiration.

The original expiration date for Jynneos vaccine is printed on its original carton label. Any subsequent expiry extensions (for commercial and SNS-deployed doses) can be found on the FDA's Expiration Dating Extension website. The updated expiration date should be written on the packaging and the vial labels along with the initials of the person making the change. Providers should also include the updated expiration date in their inventory management system. A listing of all SNS-deployed Jynneos lots with their expiration dates can be found on SNS's Monkeypox Vaccines and Treatment website.

Beyond-Use Date (BUD)

Per the Jynneos package insert, the standard beyond-use date (BUD) after thawing is 4 weeks when the intact, unpunctured vials are maintained at 2°C–8°C. To allow operational flexibility for maximal use of vaccine, the FDA amended the EUA to authorize up to 8 weeks of BUD on certain lots of Jynneos when kept refrigerated after thawing. The 8 weeks of BUD apply to the **four lots** that received expiry extension to August 21, 2026: **FDP00017, FPD00018, FDP00019,** and **FPD00020**.

Providers should track the BUD to ensure vaccine is not used after the BUD has been reached. CDC has product-specific storage and BUD labels to help providers comply with vaccine storage requirements.

Key BUD Guidance

- The BUD must not exceed the expiration date of the vaccine.
  - If the expiration date is **before** the calculated BUD, the expiration date is the final date of use.
  - If the expiration date is **after** the calculated BUD, the BUD should be written on the original packaging and the vial label, along with the initials of the person making the calculation.
- If a frozen Jynneos vial is intended for intradermal administration*, it will have two BUDs:
  - When a vial is thawed (i.e., moved from the freezer to the refrigerator), an 8-week BUD begins.
  - Once the thawed vial is first punctured, the 8-week BUD is replaced by a 8-hour BUD.
- For complete details, refer to the Jynneos Storage and Handling Summary in this addendum.

* The FDA-approved standard regimen is a 0.5 mL subcutaneous dose for persons ages 18 years and older. Under the EUA, a 0.5 mL subcutaneous dose may be administered to persons under the age of 18 years, and a 0.1 mL intradermal dose may be administered to adults aged 18 years and older. From August 2022 to February 2023, the intradermal route was preferred to extend vaccine supply while maintaining immunogenicity. Because vaccine supply is adequate now, providers can preferentially administer Jynneos via the subcutaneous route.

Jynneos Storage and Handling Summary

Product: Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-replicating)

Manufacturer: Bavarian Nordic A/S

Manufacturer Website: jynneos.com

Manufacturer Phone Number: 1-844-422-8274

Manufacturer's Package Insert and Supporting Documents:
www.fda.gov/vaccines-blood-biologics/jynneos

Emergency Use Authorization (EUA) Documents:
www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#monkeypoxvaccines

CDC's Clinical Considerations for Monkeypox Vaccines:
www.cdc.gov/monkeypox/hcp/vaccine-considerations/vaccination-overview.html

Vaccine Storage

Jynneos (one-vial presentation) can be stored in either a freezer or refrigerator, following routine storage and handling guidance in CDC's *Vaccine Storage and Handling Toolkit*. Keep vials in their original packaging to protect them from light. Follow specific guidance for each storage condition below:

- **Frozen:**
  - Unpunctured vials may be stored frozen between -25°C and -15°C (-13°F and +5°F) until the expiration date.
    - Note: Jynneos has a narrower storage temperature range than many frozen vaccines, some of which can be kept as cold as -50°C (-58°F). If you store Jynneos alongside other frozen vaccines, **ensure the storage unit temperature does not fall below -25°C.**
- **Refrigerated:**
  - Unpunctured vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for 4 weeks after thawing. Certain lots may be stored in the refrigerator between 2°C and 8°C for 8 weeks after thawing.
    - Use vaccine vials stored in the refrigerator before removing vials from the freezer.
    - Do not re-freeze a vial once it has been thawed.
    - Track the BUD by using CDC's Jynneos BUD label.
- Because Jynneos is approved for use as a single-dose vial, it does not contain preservatives. If intradermal administration is necessary, vials must be used or discarded after 8 hours of initial vial puncture. Punctured vials must be labeled with the calculated BUD and staff initials and stored at refrigerated temperatures (between 2°C and 8°C). Return the vial to the refrigerator after drawing up each intradermal dose.

Vaccine Transport

- **Frozen (preferred):**
  Jynneos vaccine should be transported frozen between -25°C and -15°C (-13°F and +5°F) within 72 cumulative hours. For example, vaccine transported for 2 hours today has 70 hours of transport time remaining.
  - Transport by using a portable freezer or qualified container and packout (appropriate packing materials) with a digital data logger (DDL) to maintain temperatures between -25°C and -15°C (-13°F and 5°F).
  - Use a temperature log for frozen transport to record vaccine temperatures during transport and the hours remaining for transport.
  - After reaching the destination, store vaccine upright in the
    - Freezer between -25°C and -15°C (-13°F and 5°F) until the expiration date, if freezer capacity is available.
    - Refrigerator between 2°C and 8°C (36°F and 46°F), if a freezer is not available.
  - When vaccine transport has been completed for the day, remove any remaining vials from the portable freezer or transport container and immediately put them in the appropriate storage unit. Note: **Thawed vaccines must never be refrozen**.
- **Refrigerated:**
  If frozen temperature condition isn't available, Jynneos vaccine may be transported between 2°C and 8°C (36°F and 46°F) for **12 cumulative hours.** For example, vaccine transported for 2 hours today has 10 hours of transport time remaining.
  - Transport by using a portable refrigerator or qualified container and packout with a digital data logger (DDL) to maintain temperatures between 2°C and 8°C (36°F and 46°F).
  - Use a temperature log for refrigerated transport to record vaccine temperatures during transport and the hours remaining for transport.
  - After reaching the destination,
    - Unpunctured vials should be stored upright in the refrigerator between 2°C and 8°C (36°F and 46°F).
    - Punctured vials should be labeled with the calculated BUD and staff initials and stored upright in the refrigerator between 2°C and 8°C.
  - When vaccine transport has been completed for the day, remove any remaining vials from the portable refrigerator or transport container and immediately put them in the refrigerator.

Vaccine Preparation

Each vial contains one subcutaneous dose (0.5 mL) or up to five intradermal doses (0.1 mL per dose).

- Frozen vaccine must be thawed 10 minutes prior to use, at refrigerated or room temperature.
- With the vial upright, gently swirl the vaccine for at least 30 seconds.
- Examine the vaccine. It should be a milky, light yellow to pale white colored suspension. Do not use if the liquid contains particulate matter or is discolored.
- Determine the route of administration based on the licensed or EUA indication:
    - **Subcutaneous (subcut)** administration* involves injecting the vaccine into the fatty tissue, typically over the triceps, in persons ages 12 months and older, or in the anterolateral thigh for persons younger than age 12 months.
        - Use each single-dose vial to obtain one 0.5 mL dose for subcutaneous administration.
        - Use a 23–25 gauge, 5/8-inch needle to withdraw one 0.5 mL dose into a sterile syringe. Always use a new, sterile needle and a new, sterile syringe for each injection.
    - **Intradermal (ID)** administration* involves injecting the vaccine superficially between the epidermis and the hypodermis layers of the skin. For Jynneos, the typical injection site is the volar (inner) aspect of the forearm, but it may also be administered in the upper back below the scapula or at the deltoid.
        - Use each single-dose vial to obtain up to five 0.1 mL doses for intradermal administration by puncturing the vial stopper five times. The number of doses varies depending on the needle and syringe combination used.
        - Use a 26–27 gauge, 1/4-, 3/8-, or 1/2-inch needle with a short bevel to withdraw one 0.1 mL dose into a sterile 1 mL syringe. Always use a new, sterile needle and a new, sterile syringe for each injection.
        - Beyond-use time: Once first punctured and an intradermal dose is withdrawn, label the vial with the calculated BUD and staff initials and store it at 2°C to 8°C (36°F to 46°F) for up to 8 hours. Do not refreeze thawed vaccine.
        - Discard the vial when there is insufficient vaccine to obtain a complete 0.1 mL intradermal dose. Do not combine residual vaccine from multiple vials to obtain a dose.

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