Vaccine Storage and Handling Toolkit

Mpox Vaccines Addendum

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MPOX VACCINES STORAGE AND HANDLING

This addendum to the *Vaccine Storage and Handling Toolkit* (March 2024) provides information, recommendations, and resources to assist Mpox providers with properly storing and handling Mpox vaccines to meet the requirements of the HHS Mpox Vaccination Program Provider Agreement. The toolkit brings together best practices from the General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies. Implementing the toolkit best practices and recommendations will help to safeguard the vaccine supply and ensure patients receive safe and effective vaccines.

This addendum provides information on storage and handling best practices for Mpox vaccine. Specific, detailed storage and handling protocols for individual Mpox vaccines are provided in manufacturer package inserts for vaccines licensed by the Food and Drug Administration (FDA). However, some Mpox vaccines such as Jynneos are currently authorized for use under an EUA so vaccination providers should refer to both the EUA and the manufacturer information for detailed storage and handling information for each vaccine.

Vaccination Provider Requirements

All mpox vaccination providers participating in U.S. Monkeypox Vaccination Program are required to sign a Vaccination Program Provider Agreement to receive delivery of the mpox vaccine from the distributor or a vaccine manufacturer. The agreement must be completed by all public and private providers, provider organizations, and government-affiliated federal, state, territorial, and local providers.

As part of the agreement, providers are required to:

- Store and handle vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in this toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in this toolkit.
- Comply with immunization program guidance for handling temperature excursions. Monitor and comply with vaccine expiration dates and beyond-use dates/times.
- Preserve all records related to vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of vaccine, including unused doses.

Emergency Use Authorization Storage and Handling Information

There are two vaccines (JYNNEOS and ACAM 2000) available for the prevention of Mpox. Both vaccines are licensed by the Food and Drug Administration (FDA). Jynneos is approved for the prevention of smallpox and Mpox, and ACAM 2000 is approved for smallpox. Jynneos should be administered subcutaneously but can also be administered intradermally for persons >18 years of age if circumstances require that (e.g., a shortage of vaccine). FDA has also authorized emergency use of Jynneos for intradermal administration in adults and subcutaneous administration in children. Vaccination providers should refer to manufacturer package insert for each vaccine storage and handling information. Also refer to EUA fact sheet or other relevant FDA-authorized information.

Vaccine Cold Chain

Vaccines require a temperature-controlled environment. A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. It begins with vaccine manufacturing and ends with vaccine administration. Vaccines must be stored properly from the time they are manufactured until they are administerd. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

An effective cold chain relies on three main elements:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions.

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Staff and Training

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and procedures. As a resource for staff, this toolkit highlights storage and handling best practices to help protect the vaccine supply. In addition, CDC's *You Call the Shots*: Vaccine Storage and Handling is a free, online training module focused on storage and handling requirements. Jurisdictions may also have specific requirements for storage and handling training, policies, and procedures.

All facilities must designate a primary vaccine coordinator and an alternate (backup) coordinator who will be responsible for ensuring all vaccines are stored and handled correctly. The primary and alternate vaccine coordinators should be experts on your facility's storage and handling procedures.

See Section Two, "Staff and Training, (page 7)" in the toolkit for more detailed information.

CDC recommends developing and maintaining clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide direction for handling emergencies such as equipment malfunctions, power failures, or natural disasters.

Vaccine Storage and Temperature Monitoring Equipment

Mpox vaccination providers must have proper storage and temperature monitoring equipment to meet the specific needs of the vaccine product(s) in their inventory. This includes the correct vaccine storage unit(s), whether a refrigerator or regular freezer. Purpose-built, also referred to as "pharmaceutical-grade," units are preferred and designed specifically for storage of biologics, including vaccines. However, household-grade units can be an acceptable alternative in some situations.

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

It is essential that each vaccine storage unit has a temperature monitoring device (TMD) to ensure that vaccines are stored within the correct temperature range. CDC requires a specific type of TMD called a "digital data logger" (DDL) to monitor mpox vaccines. A DDL provides the most accurate storage unit temperature information. Additionally, in the event of a temperature excursion (temperatures outside the correct range), a DDL can indicate how long and the temperatures the vaccine has been exposed to. This information is needed to determine the viability of the vaccine.

Always use a DDL that can continously monitor storage unit temperatures and has a:

- Buffered temperature probe
- Current and valid certificate of Calibration Testing

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Temperature Monitoring Requirements

Staff must check and record temperatures at the beginning of each workday to determine if any excursions have occurred since the last temperature check.* Monitor and record storage unit temperatures following one of these options.

When recording include:

- Minimum/maximum temperature†
- Date
- Time
- Name of person checking and recording temperature
- Actions taken if a temperature excursion occurred

Food and beverages should never be stored in the unit with vaccines. If other immunobiologics are stored in the unit, vaccines should be stored on the shelf above them.

CDC has temperature logs that can be used for recording this information. Temperature records must be kept for a minimum of three years, or longer if required by your jurisdiction.

Storing vaccines correctly in a vaccine storage unit is also critical to protect the vaccine and protect the vaccine from losing their potency if Mpox vaccine are stored with other vaccines. Best practices include:

- Place water bottles on the top shelf, floor, and in the door racks of vaccine storage units to help maintain stable temperatures that might be disrupted by frequently opening and closing unit doors. (Note: Water bottles are not recommended for use in in ultra-cold freezers or in all purpose-built or pharmaceutical-grade units—see manufacturer guidance.)
- Avoid placing or storing any items other than vaccines, refrigerated diluents, and water bottles inside storage units.
- Store vaccines and diluents in original packaging.
- Position vaccines and diluents two to three inches from the storage unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow.
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation.
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.

To help providers track expiration dates and beyond-use dates (BUDs), visit the Administration for Strategic Preparedness and Response (ASPR) to track expired vaccines. Also note that expiration dates may change as additional stability data become available. In addition, Mpox vaccine must be used within a certain time frame (beyond-use date) if moved from one state to another (e.g., frozen to refrigerated). Providers should monitor/track the BUD to ensure vaccine is not used after the BUD has been reached.

See Section Three, "Vaccine Storage and Temperature Monitoring Equipment, (page 9)" for more detailed information about storage units, temperature monitoring equipment, and vaccine placement in vaccine storage units.

* Monitoring requirements may vary if you are using the manufacturer-provided shipping container for storage.
† If the DDL cannot display the minimum/maximum temperatures, record the current temperature at the beginning and end of each work day.

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"Temperature Excursions"

Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action. To determine whether a vaccine is likely to still be viable, vaccine manufacturers will analyze information about the magnitude of the temperature excursion, including the total amount of time that temperatures were out of range. To provide the manufacturer with sufficient information to determine vaccine viability, CDC requires taking the following steps after a temperature excursion:

- Label the vaccine "Do Not Use" and store at the recommended temperature range until you receive manufacturer guidance. If it is a frozen vaccine that has been thawed, store in the refrigerator between 2° C and 8° C (36° F and 46° F) until you receive manufacturer guidance, as refreezing the vaccine may damage it.
- Document the date and length of time of the excursion, the storage unit temperature (minimum/maximum, if available), and inventory affected.
- Record any other relevant information.
- Contact the manufacturer and/or immunization program for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination.
- Document the event and actions taken for record-keeping requirements.

It is important to note that vaccine manufacturer responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Different information about the same event can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations cannot be applied to future events that may appear similar to past events. For manufacturer contact information for vaccine- and temperature-related questions, see the Mpox vaccines-specific product information page in this addendum.

See Section Three, "Vaccine Storage and Temperature Monitoring Equipment, (page 9)" for more additional information about recording and reporting temperature excursions.

Vaccine Deliveries and Vaccine Inventory Management

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, ensuring your facility has the vaccines your patients need.

Maintaining the cold chain is the first step in vaccine inventory management. Vaccine deliveries must only be scheduled at times when staff is guaranteed to be present because vaccines can never be left unattended. To support efficient distribution of vaccine, full-day receiving hours should be available. When that is not possible, locations receiving vaccine and ancillary supply shipments must be available during a four-hour window on a weekday other than Monday. Deliveries of Mpox vaccine do not require a signature.

Upon arrival, all shipments of vaccine must be immediately examined for signs of damage, for indication of a temperature excursion during transit, and to confirm receipt of the appropriate vaccine types and quantities. Before opening a vaccine shipment, ensure the vaccine is immediately:

- Stored at recommended storage conditions.
- Documented using your facility's vaccine inventory management process.

Vaccine inventory accounting includes keeping stock records to determine the type and amount of mpox vaccine your facility should stock to meet the needs of your patients. It also involves checking expiration dates regularly and rotating stock so that doses with the earliest expiration dates are placed in front of those with later dates.

JYNNEOS MPOX vaccine shipments do **NOT** include ancillary supplies.

ACAM2000 vaccine is shipped with bifurcated needles

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

See Section Four, "Vaccine Inventory Management, (page 18)" for additional information about vaccine inventory accounting measures.

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Expired Vaccine

Determining when a vaccine or diluent expires is a critical step in proper storage and handling.

Expired vaccines and diluents must be removed immediately from storage units to avoid inadvertently administering them. Manufacturers may have specific guidance on how to handle expired or compromised vaccines. However, open or broken vials and vaccine predrawn by providers cannot be returned and must be discarded according to your jurisdiction's requirements.

To help vaccination providers track expiration dates and beyond-use dates (BUDs), CDC has developed product specific tracking tools and labels:

- Mpox Vaccine

Vaccine Disposal

Medical waste disposal requirements are set by state environmental agencies and may vary from state to state. Your jurisdiction's immunization program or environmental agency can provide guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations. Vaccine manufacturers should also provide guidance about proper disposal of their products, including any unused vaccine. In some instances, unused vaccine may be returned to the manufacturer. Empty vaccine vials are usually not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with your jurisdiction's requirements for disposal.

Vaccine Preparation

Preparing vaccine properly is critical to maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and, ultimately, to the patient. CDC recommends preparing and drawing up vaccines just before administration. It is important to follow vaccine preparation instructions provided in the vaccine product's Fact Sheet for Vaccination Providers or the manufacturer package insert.

Vaccine products may have different preparation requirements. Some should not be shaken, or the vaccine will be compromised and cannot be used. Carefully follow the manufacturer's vaccine preparation guidance. Diluents, if applicable, are not interchangeable unless specified by the manufacturer. Vaccine mixed with the wrong diluent should never be administered.

Vaccine Preparation Best Practices

- » Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- » Always follow the manufacturer's instructions for preparing vaccine.
- » Only prepare vaccines when you are ready to administer them.
- » Always check expiration dates. If your facility stocks multiple vaccine products, always confirm you have selected the correct vaccine.
- » Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

Predrawing vaccine can result in waste when more is drawn up than needed. In the rare instances when it is necessary to predraw vaccines, it is important to follow recommended guidance to avoid compromising and wasting vaccine and to maintain the cold chain. Carefully follow the toolkit best practices for predrawing vaccine as well as any manufacturer guidance.

See Section Five, "Vaccine Preparation, (page 21)" for detailed information about vaccine preparation.

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Mpox Vaccine Transport

Mpox vaccine is shipped from Strategic National Stockpile (SNS) sites to vaccine depots. Before storing vaccine,

A partially used vial cannot be transferred from one provider to another or across state lines.

- Examine the shipment for signs of damage.
- Check TempTale temperature monitoring device or DDL for temperature excursions.

If vaccine needs to be further transported (i.e., from vaccine depots to health departments or clinics), unpack vaccine from Credo Crates and repackage into an appropriate transport system as outlined in the Transport guidance here. Expiration date should be recorded when vials are separated from original packaging.

Vaccine must only be transported using appropriate packing materials that provide maximum protection. Follow specific jurisdiction and federal direction for transporting vaccine products.
Transporting vaccine requires planning and preparation to ensure the cold chain is maintained. As a vaccination provider, you should carefully review Section Six, "Routine Vaccine Transport," to ensure your facility has the appropriate procedures and supplies in place to safely transport vaccine. Transport guidance may vary based on the specific vaccine product.

The charts shows transport in two situations: routine transport and emergency transport to maintain the vaccine cold chain during transport for use at off-site clinics or satellite facilities or for relocation of stock. Recommendations vary based on the situation. Some vaccine products may have specific transport guidance to ensure the cold chain is maintained and vaccine is protected. Refer to the relevant vaccine product information in this addendum for additional information.

Emergency Transport System Recommendations

Container	Emergency Transport
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System	Yes
Manufacturer's Original Shipping Container	Yes
Food/Beverage Coolers	No

Routine Transport System Recommendations

Container	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System	No
Manufacturer's Original Shipping Container	No
Food/Beverage Coolers	No

Emergency Storage and Handling

Emergencies such as equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise storage conditions. It is critical that vaccination providers have plans in place for emergency situations. Some key issues to remember include:

- Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.
- Having an on-site generator(s) prevents the need to transport vaccines to an alternative storage facility during a power outage.
- Emergency situations can arise outside of normal business hours, so your office staff as well your facility's building manager and/or security staff, if appropriate, must understand how to implement your emergency operation plans or access your facility if necessary.
- Ensure your facility has the resources on hand to safely pack vaccines for transport during emergencies.

See Section Seven, "Emergency Vaccine Storage and Handling, (page 27)" for additional information about monitoring and handling vaccine during an emergency.

Additional Resources

- *General Best Practice Guidelines for Immunization*: www.cdc.gov/vaccines/hcp/ acip-recs/general-recs/index.html
- Educational webinars and continuing education for healthcare providers: www.cdc.gov/vaccines/ed/courses.html
- Emergency Use Authorization: www.youtube.com/watch?v=iGkwaESsGBQ&feature=youtu.be
- *Epidemiology and Prevention of Vaccine-Preventable Diseases*: www.cdc.gov/vaccines/pubs/pinkbook/index.html
- FDA Center for Biologics Evaluation and Research (CBER) information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/
- Federal Emergency Management Agency (FEMA) information on disaster preparedness: www.fema.gov/
- Immunization Action Coalition Refrigerator and Freezer Temperature Log Sheets and Vaccine Troubleshooting Record: www.immunize.org/va/va52_temperature-logs-iac.pdf
- Jurisdiction immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html
- Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
- *You Call the Shots*: Vaccine Administration: www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp
- *You Call the Shots*: Vaccine Storage and Handling: www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp
- Vaccine Administration home page: www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- Vaccine Storage and Handling home page: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html (sign up for notifications about updates)
- *Vaccine Storage and Handling Toolkit* web page: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Disclaimer: *Use of trade names and commercial sources in the addendum is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). You may see vendors use terms such as "CDC-compliant," or "satisfies federal COVID-19 vaccine response requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC has independently assessed and verified the quality of these products. CDC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that CDC has not validated any product or service for compliance with vaccination provider requirements or standards as outlined in the COVID-19 and Mpox Vaccination Provider Agreement.*

MPOX Vaccine (JYNNEOS)

Product: JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating)
Manufacturer Website: jynneos.com
Manufacturer Phone Number: 1-844-422-8274
CDC Clinical Guidance for Mpox Vaccine: www.cdc.gov/poxvirus/mpox/clinicians/vaccines/vaccine-considerations.html

Vaccine Temperature Range:

Unpunctured vials may be stored:

- Frozen: Between -25°C and -15°C (-13°F and 5°F) until the expiration date
- Refrigerated: Between 2°C and 8°C (36°F and 46°F) for up to 8 weeks. This is different from the 4-week storage at 2°C and 8°C mentioned in the package insert and is allowed per FDA-issued EUA.

Punctured vials may be stored:

- Refrigerated between 2°C and 8°C (36°F and 46°F) for up to 8 hours after first puncture, if being used for intradermal doses.

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine is shipped from Strategic National Stockpile (SNS) sites to vaccine depots.
- JYNNEOS is shipped frozen from SNS to vaccine depots/sites upfront prior to the 2 vaccine storage options upon receipt - frozen for longer-term or refrigerated for only up to 8 weeks.
- Vaccine arrives frozen between -25°C and -15°C (between -13°F and 5°F)
- Examine the shipment for signs of damage. Each box contains 20 vials.
- Each box has a TempTale temperature monitoring device or DDL that should be checked following SNS guidance.
- If vaccine needs to be further transported (i.e., from vaccine depots to health departments or clinics), unpack vaccine from Credo Crates and repackage into an appropriate transport system as outlined in the Transport guidance below. Expiration date should be recorded when vials are separated from original packaging.

Storage Information: Vaccine can be stored in a freezer or refrigerator following routine storage and handling best practices. Individual guidance for each storage unit is as follows:

Freezer

Unpunctured vials may be stored frozen between -25°C and -15°C (-13°F and 5°F) until the expiration date.*

- » The expiration date may be extended as more stability data become available. As the expiration date approaches, contact the manufacturer to determine if the expiration date has been extended prior to discarding vaccine.
- » Store vaccine vials upright in the original package when possible.
- » Protect vaccine from light.

* These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is narrower. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

MPOX Vaccine (JYNNEOS)

Refrigerator

Unpunctured vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks from thawing. This updated information has been provided by the vaccine manufacturer based on available supportive stability data. Please note that this differs from the package insert, which states that the vaccine may be kept at 2°C to 8°C (36°F to 46°F) for 12 hours (Section 2.2 Preparation and Administration and 16.2 Storage Conditions).

- Once thawed, vaccine cannot be refrozen.
- Use CDC's JYNNEOS beyond-use date (BUD) labels to track how long the vaccine has been in the refrigerator.
  - If the expiration date shown on the carton is earlier than the 8 weeks after vial was first thawed, write the expiration date on the box or container holding the vaccine vials. Note: the web posting of the expiration dates by lot numbers refers to JYNNEOS is kept frozen.
- Store vaccine vials upright.
- Protect vaccine from light.
- Use vaccine vials stored in the refrigerator before removing additional vials from the freezer.

Punctured vials should be stored at refrigerated temperatures (between 2°C and 8°C) for up to 8 hours. Place the vial back in the refrigerator after drawing up each intradermal dose. Do NOT leave vaccine vial out at room temperatures in between doses.

Transport:

Frozen transport is preferred if vaccine must be transported.

Frozen transport:

JYNNEOS vaccine may be transported frozen at -25°C and -15°C (-13°F and 5°F) for 72 cumulative hours (e.g., vaccine transported for 2 hours today has 70 hours of transport time remaining).

- Transport using a portable freezer or qualified container to maintain between -25°C and -15°C (-13°F and 5°F) with DDLs.
- When you have completed the vaccine transport for the day, remove any remaining vials from the transport container, and place vials immediately in freezer.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport.
- 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, or in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks from thawing.

Refrigerated transport:

JYNNEOS vaccine may be transported at 2°C and 8°C (36°F and 46°F) for 12 cumulative hours (e.g., vaccine transported for 2 hours today has 10 hours of transport time remaining).

- Transport using a portable refrigerator or qualified container to maintain between 2°C and 8°C (36°F and 46°F) with digital data loggers.
- When you have completed vaccine transport for the day, remove any remaining vials from the transport container and then place vials immediately in refrigerator.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport.
- Store vaccine upright in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 8 weeks.

MPOX
Vaccine (JYNNEOS)

Vaccine Preparation and Administration:

- Each vial contains one subcutaneous dose (0.5 mL) or approximately five intradermal doses (0.1 mL).
- Under this EUA, each single dose vial may be used to obtain up to five 0.1 mL doses for intradermal administration using five punctures of the vial stopper with an appropriate needle for administration; this is expected to vary depending on the needle and syringe combination that is used.
- Discard vial when there is not enough vaccine to obtain a complete intradermal dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Frozen vaccine must be thawed at room temperature for 10 minutes before using.
- Do **NOT** refreeze thawed vaccine.
- 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.
- Once punctured, the vaccine must be stored in the refrigerator and used within 8 hours.
- Administer by subcutaneous or intradermal injection.

Special Considerations:

- Unpunctured vials may be held at room temperature for up to 6 cumulative hours. No additional stability data at room temperature is available.
- Do not use vials held at room temperature for longer than 6 hours. Facilities should dispose of the product and maintain disposal records according to their local facility's disposal policies and state regulations. Jurisdictions should maintain records of product lot numbers and quantities that are destroyed.