

Smallpox/Monkeypox Virus (hMPXV) Vaccine Considerations

General Actions
<input type="checkbox"/> Review and implement all storage and handling recommendations in CDC's Vaccine Storage and Handling Toolkit , which is available on CDC's Vaccine Storage and Handling Resources webpage
<input type="checkbox"/> Review additional CDC Vaccine Storage & Handling training video <ul style="list-style-type: none"> ○ Additional CDC Vaccination training videos are available here
<input type="checkbox"/> Review the JYNNEOS™ Package Insert and EUA Fact Sheet for Healthcare Providers
<input type="checkbox"/> Review Smallpox/Monkeypox (hMPXV) Vaccine Information Sheet (VIS) and EUA Fact Sheet for Vaccine Recipients and Caregivers
<input type="checkbox"/> Review CDC's Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak and Interim Guidance for JYNNEOS Vaccine
<input type="checkbox"/> Review Standing Orders: <ul style="list-style-type: none"> ○ For Monkeypox Virus (hMPXV) Vaccine – JYNNEOS™ – please be advised this does not cover persons < 1 year of age ○ For Medical Management of Vaccine Reactions in Adults in a Community Setting ○ CDC Standing Order templates for alternative dosing regimen (intradermal) and standard regimen (subcutaneous)
<input type="checkbox"/> Review CDC's Safe Injection Practices
<input type="checkbox"/> Review JYNNEOS™ Preparation and Administration information: <ul style="list-style-type: none"> ○ Standard Regimen Summary (subcutaneous) ○ Alternative Dosing Regimen Summary (intradermal) ○ Additional administration details (including training video and images for intradermal)
<input type="checkbox"/> Prepare to submit vaccine administration data into the New Jersey Immunization Information System (NJIS) <ul style="list-style-type: none"> ○ Options: HL7 interface with NJIS or direct (manual) data entry ○ The interface enrollment form will need to be submitted for HL7 interface
Smallpox/Monkeypox (hMPXV) Vaccine Storage Information
<input type="checkbox"/> Ensure vaccine storage units meet CDC specifications and temperatures are monitored using digital data loggers (DDL) at all times <ul style="list-style-type: none"> ○ Storage units must be: <ul style="list-style-type: none"> ● Pharmaceutical grade or purpose built ● Household grade refrigerator with separate, stand-alone freezer ○ Do not use the freezer section of a combination household unit to store vaccines ○ NEVER use a dormitory-style refrigerator to store vaccines, even temporarily!
<input type="checkbox"/> Ensure contingency plans are in place for appropriate handling of vaccines during a disaster or power outage <ul style="list-style-type: none"> ● Refer to JYNNEOS™ Storage and Handling Summary ● JYNNEOS™ is shipped at -20°C and requires cold chain management ● JYNNEOS™ should be stored frozen at -25°C to -15°C (-13°F to +5°F) - please refer to the package insert for more detailed storage requirements for this vaccine. <ul style="list-style-type: none"> ○ For immediate administration, JYNNEOS™ vials can be thawed at ambient temperature - thawing a vial at ambient temperature should take less than 10 minutes when the vial is taken from -20°C. ○ If not for immediate administration, the frozen vials can also be removed from the -20°C storage to 2-8°C storage to maintain until use <ul style="list-style-type: none"> ● Unopened vials of JYNNEOS™ may be stored at 2-8°C up to 8 weeks from thawing (please be aware that this differs from the package insert – see Provider Letter) ● Punctured vials must be discarded 8 hours after puncture <ul style="list-style-type: none"> ▪ Maintain at refrigerator temperature after first puncture

- If vaccine is being transported to another facility, it must be done so **ONLY** using a **qualified container/packout** for transfers and **DDLs**; transporting vaccines in a cooler is unacceptable
 - [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#)
- Manufacturer information for JYNNEOS™/Imvamune/Imvanex (CPT Code: TBD; CVX Code: 206)
 - [Bavarian Nordic A/S](#)
 - Phone: 1-800-675-9596
 - Email: info@bavarian-nordic.com

Temperature Monitoring – Digital Data Loggers (DDL)

- Ensure that DDLs meet CDC specifications. A DDL is required for each permanent and temporary storage unit ⁱ
- DDLs must have current and valid Certificates of Calibration ⁱⁱ
- Learn how to access and download your DDL data. It must be checked at least weekly and temperature data must be kept for a minimum of 3 years
- Place DDLs in each storage unit. Review/download data at least weekly, whenever an alarm sounds, and whenever an out-of-range current or min/max temperature is noted
 - Ensure alarms are set correctly. DDLs should alarm **before** a temperature excursion would occur, so you can correct the issue before the vaccines are exposed to an out-of-range temperature (for example set minimum at 2.5°C and maximum at 7.5°C, so you can take action to keep the refrigerator in 2-8°C range)
 - Set device to record at least every 30 minutes
 - Ensure a backup DDL is available
- Keep min/max temperature logs up to date and available
- Post “Do Not Disconnect” signs on outlets and circuit breakers
- Address and report all temperature excursions **immediately** to the vaccine manufacturer

Every Vaccination Visit

- Provide to patient, a copy of:
 - [EUA Fact Sheet for Patients and Caregivers](#) when administering under the EUA provisions, **OR**
 - Smallpox/Monkeypox (hMPXV) [Vaccine Information Sheet \(VIS\)](#) if administered as originally licenses
 - No consent form is required
- Provide patient with Smallpox/Monkeypox (hMPXV) vaccination record
 - For example: copy of facility vaccination record, print out of dose information from NJIIS, NJDOH yellow card
- Report Smallpox/Monkeypox (hMPXV) vaccine administration into NJIIS as soon as possible, but no later than 72 hours from administration
 - Be sure all information entered is accurate and complete. This includes all patient demographic information. Collect and enter race/ethnicity information for each patient
 - Complete charting includes the date a VIS was given to patient and the date that document was published
- Evaluate [NJIIS Consent](#) from patient, if appropriate ([English](#) or [Spanish](#))
 - Consent is required for individuals who are born before 1998 and/or are not already in NJIIS
 - For those who refuse to sign the consent form, enter doses as “administered to person not in NJIIS” to allow dose to deduct from inventory
- As of 8/9/22, per the [EUA Fact Sheet](#), providers cannot charge patients for the vaccine dose and must administer the vaccine regardless of the recipient’s ability to pay administration fees. Vaccine providers may seek appropriate reimbursement from a program or plan that covers Monkeypox (hMPXV) vaccine administration fees for the vaccine recipient (vaccine recipient’s private insurance company or Medicare/Medicaid reimbursement).
 - CPT code information can be found [here](#) and [here](#) as of July 2022

Reminders

- Download, review, and save DDL data. If you find any out-of-range temperatures, notify the manufacturer **immediately**

- Check vaccine expiration dates and rotate stock
 - Expiration dates are found on the carton but not on the vial itself. Expiration dates may also be found at: [Monkeypox \(hhs.gov\)](https://www.hhs.gov)
 - **NOTE:** If you are storing vaccine outside of the manufacturer’s recommended storage (for JYNNEOS that would be in the refrigerator) be sure to label the vials with the Beyond Use Date (BUD) which will be 8 weeks from the date the vaccine was thawed. BUD **cannot** exceed the manufacturer expiration date and vaccine should not be given to patients past the BUD.
- If an Adverse Event occurs, submit a [VAERS](#) report
 - Healthcare providers are required to report per the [EUA](#):
 - Vaccine administration errors (whether associated with an adverse event or not)
 - Serious adverse events (irrespective of attribution to vaccination)
 - Cases of cardiac events including myocarditis and pericarditis
 - Cases of thromboembolic events and neurovascular events
 - Provide a copy of the VAERS report to Bavarian Nordic at 1-800-675-9596
 - Healthcare providers are encouraged to report any clinically significant adverse events that occur after vaccination

Appendix

ⁱ DDL requirements as outlined in CDC Storage and Handling Toolkit:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon)
- Air probes are only permitted for ultra-low freezers, otherwise, probes should be buffered.
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature display outside of storage unit
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Memory for storing at least 4,000 readings
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

DDL(s) must have at least enough probes to cover the total storage unit compartments at your site.

At minimum, your site must have at least 1 back-up DDL, which is self-sustaining and portable for transport and off-site clinic use.

ⁱⁱ Certificate of Calibration requirements as outlined in the CDC Storage and Handling Toolkit:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Expiration date/Recalibration date
- Confirmation that the instrument passed testing
- Documented accuracy of +/-0.5°C (+/-1°F)
- Must be issued by an appropriate entity, which is indicated by one or more of the following:
 - Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (<+/-0.5°C or <+/-1°F)
 - Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
 - Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)