

JYNNEOS VACCINE GUIDANCE AND BEST PRACTICES



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Key Points Regarding Monkeypox Vaccine

HHS is working with Wisconsin to deploy the US Food and Drug Administration (FDA)-approved JYNNEOS vaccine.

Wisconsin is currently not pursuing the deployment nor use of the ACAM2000 vaccine.

The CDC recommends that JYNNEOS (also known as IMVAMUNE, IMVANEX, MVA) is used as an alternative to a ACAM2000 for primary orthopoxvirus vaccination and booster doses, in addition to use as preexposure prophylaxis against orthopoxvirus infection among persons at risk of such exposures.

The effectiveness of the JYNNEOS vaccine to the virus circulating in the current 2022 outbreak is unknown. To better understand the protective benefits of this vaccine during the current outbreak, data will be collected to help define JYNNEOS vaccine efficacy.

- The effectiveness of JYNNEOS against monkeypox is supported by clinical studies demonstrating a comparable immune response to ACAM2000 and animal studies.
- There are no data yet on the effectiveness of JYNNEOS for PEP, PEP++, or PrEP from the current outbreak. Although this is also true for ACAM2000, there is evidence that the precursor for ACAM2000 was effective in eradicating smallpox. Public health officials have concern about the lack of real-world effectiveness data for JYNNEOS, especially because a second dose of JYNNEOS was required in a clinical study to reach the same maximal antibody response seen with ACAM2000 at the 4-week timepoint, and a correlate of protection has not been defined (i.e., it is not known what level of antibodies is needed to prevent *Monkeypox virus* infection).

JYNNEOS is a live, attenuated, non-replicating vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating Orthopoxvirus:

- Licensed by FDA in September 2019.
- JYNNEOS is indicated for prevention of smallpox and monkeypox disease in adults **18 years of age and older** determined to be at high risk for smallpox or monkeypox infection.

Please note that HHS and DHS are not distributing ancillary supplies for monkeypox vaccine.

Vaccine Recommendations

- New 8/3/2022 review [CDC's monkeypox standing orders for administration](#) factsheet.
- CDC recommends that the vaccine be given within 4 days from the date of exposure to prevent onset of the disease.

- If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.
- A person is considered up to date 2 weeks after the second dose of JYNNEOS. [Use of JYNNEOS \(Smallpox and Monkeypox Vaccine, Live, Nonreplicating\) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR \(cdc.gov\)](#)

Vaccination Eligibility Guidance

The Wisconsin Department of Health Services (DHS) is using a hub and spoke model to distribute JYNNEOS vaccine from the Strategic National Stockpile (SNS) to vaccinators for use to control the spread of Monkeypox. The overarching goal of the distribution strategy is to ensure quick and equitable access to vaccines for those disproportionately affected by monkeypox.

The amount of vaccine available nationally is limited. DHS is receiving a limited vaccine allocation from SNS. Clinics will receive vaccine as it becomes available and likely in small amounts.

As this outbreak changes, and vaccine allocations change, the vaccine eligibility guidance will change. Please follow current vaccine [eligibility guidance for clinicians](#).

Eligibility guidance for use of JYNNEOS vaccine for Wisconsin clinicians:

- Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
- Persons having any skin-to-skin contact with a person diagnosed with Monkeypox
- Gay men, bisexual men, trans men and women, any men who have sex with men, and gender non-conforming/non-binary individuals, who have had multiple sexual partners in the last 14 days AND:
 - Having any skin to skin contact with a person diagnosed with monkeypox
 - Having sex with multiple partners
 - Having sex in exchange for money or other items
 - Having sex with one or more anonymous partners or any partner at a party, club, or other venue where sex occurs on the premises
- Depending on vaccine availability, clinicians may administer vaccine to those who may not have had exposure in the last 14 day, but who indicate they may have one of these exposures soon.

Note: As allocations increase, and the outbreak changes, the criteria of eligible individuals for vaccination will be updated.

People with a known or suspected exposure to a suspected or confirmed monkeypox case in the past 14 days should work directly with their local health department (LHD) to discuss obtaining the JYNNEOS vaccine as quickly as possible.

Screening and Consent

Give every patient who receives the vaccine a vaccine information sheet (VIS) ([English](#) and [Spanish](#)). Please visit immunize.org for VISs in additional languages. Prior to vaccine administration, ensure the patient understands the risks and benefits of vaccination.

Please follow your organization's typical policies and processes for gaining patient consent prior to vaccination. DHS does not require any specific method of obtaining patient consent.

DHS asks that you follow the vaccine [eligibility guidance](#) when determining who to vaccinate. Patients do not need to complete a physical copy of the DHS form, but please establish a protocol to ask patients the questions outlined.

Vaccine Inventory Management

- Designate one or two people to manage inventory.
- Designate certain people who can remove inventory from the storage unit.
- Rotate inventory based on the earliest expiration date. Check expiration dates weekly, or as new allocations arrive.
 - The label expiration is set to expire at the end of the calendar month. For example, on the label, an expiration date of 9/22 would indicate September 30, 2022, as the expiration date.
- Keep the doses in their original packaging or amber colored bag.
 - If you need to split a box, place doses in an amber colored bag and make a copy of the lot number, NDC, and expiration date. Store the copy in your storage unit with the first doses in the amber bag.
 - Limit splitting boxes.
- Inventory in WIR must be kept up to date.
- Given the current vaccine supply issues, it is recommended that you use an appointment-based system (versus open walk-in clinics) to ensure that you do not need to turn many individuals away due to demand outstripping vaccine supply.

Second Dose Allocations

Beginning August 5, 2022, approved vaccinators can administer all vaccine allocated as first doses and should not hold any supply back as second doses. However, JYNNEOS is still a two-dose series and vaccinators should work with individuals to schedule second dose appointments as vaccine supply allows. People should receive the second dose no sooner than four weeks after the first dose. This strategy aims to provide some level of protection against monkeypox to as many people as possible by allowing vaccinators to not hold back any available vaccine.

Recalling Patients for Their Second Dose

Ensuring patients receive two doses of JYNNEOS vaccine is important for ensuring they are fully protected. Clinics should implement systems to support and remind patients of their second dose. Below are suggestions for ensuring patients return.

- Provide counselling and education about the importance of completing the two-dose series on-time for the best protection.
 - Patients need to know that they are not fully protected until 14 days after their *second* dose.
 - They should continue to take precautions against monkeypox during this time.
- Collect contact information at the time of the first dose and let patients know they will receive reminders from your clinic and how they can expect to receive reminders (for example, tell them to check their electronic medical record, or someone from the clinic will reach out).
- Send reminders for patients to come in by using phone, email, text or mailed letters in advance of the appointment in the patient's preferred language.
 - Use whatever communication method is most effective and/or the preference of your patients.
- Patients who missed second dose appointments or are over-due should be contacted and rescheduled immediately.
- Learn how to use WIR to support your reminder efforts by reviewing the [WIR Reminder/Recall reports](#) handout.
- **Important:** Work with your organization and programs in your area to ensure structural issues such as transportation, language, childcare, and time from work are not barriers to receiving the vaccine.

Redistribution

In general, healthcare providers cannot redistribute monkeypox vaccine to other healthcare providers. If there are questions about redistribution, or if a healthcare provider has extra vaccine, please email DHSMonkeypoxVaccine@wi.gov.

JYNNEOS Vaccine Storage

- New 8/3/2022 Review the CDC's [JYNNEOS Smallpox and Monkeypox Vaccine Storage and Handling Summary](#).
- Keep frozen at -25°C to -15°C (-13°F to +5°F).
- JYNNEOS is light sensitive. Store in the original package or an amber bag to protect from light.
 - If storing in an amber bag, copy the expiration date, lot number, and NDC and store it with the bag.
- Do not re-freeze a vial once it has been thawed.
- Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks.
 - Please note that clinics should follow the storage guidance in the "[Dear Provider Letter](#)"

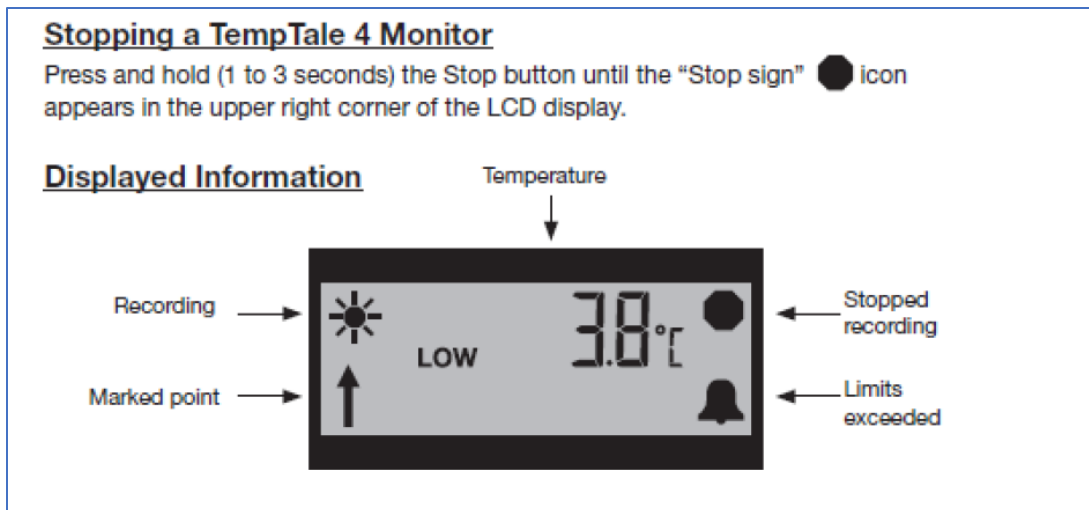
- Do not use the vaccine after the expiration date.
 - Note the expiration date is not shown on the individual vial
 - You can validate the expiration dates on the [HHS](#) website.
- Use the [CDC JYNNEOS Storage and Handling summary](#).

New 8/4/2022 Cold Chain Product Handling

Your cold chain shipment will arrive in a specially designed cold chain shipping container called a CREDO. Inside the CREDO, there will be a temperature monitoring device called a TempTale Bio monitor. Using the two correctly will ensure you have a viable product to prevent illness and save lives.

Cold Chain handling Instructions

1. Open the Credo cold chain shipping container.
2. View the TempTale and record the temperature you see as it may be important later.
3. Stop the TempTale monitor by pressing the STOP button for 1-3 seconds.
4. View the TempTale LCD to look for the bell shaped “Limits Exceeded” icon as shown below. If you do not see the limits exceeded icon, your product is cleared for use. Please move on to step 6 and return the TempTale and Credo to SNS.
5. If you DO see the limits exceeded icon (bell symbol), push and hold (approximately 3-5 seconds) the green START button to begin to take a close-up picture of EACH of the 5 readings displayed on the TempTale LCD screen and forward the pictures to SNS by replying to all in the email that provided your ETA. SNS staff will review the images and work to determine whether the product is cleared for use or if you need a replacement shipment.
6. As soon as you can, repackage the TempTale into the CREDO container, and send both back to the SNS using the return shipping label. If you did not receive a return shipping label, notify SNS immediately by “Reply to All” to the email that provided your ETA.



Note that the Jynneos Use During Monkeypox Response: Vaccine Accountability Form provided by CDC is no longer needed.

Storage Temperature Excursions

As vaccine arrives at your clinic, please verify the vaccine temperature was maintained throughout the delivery process.

All temperature excursions-both enroute to your clinic or in your clinic's storage unit-must be reported to the manufacturer to determine vaccine viability. **DO NOT** use vaccine that has experienced a temperature excursion until viability has been determined.

Steps to determine viability

1. Quarantine the vaccine **in your storage unit** and mark "do not use" until you receive a determination report from the manufacturer.
2. Contact Bavarian Nordic at toll-free phone 1-800-675-9596.
 - a. General questions on temperature excursions can be sent to DHSMonkeypoxVaccine@wi.gov
3. If the determination report indicates the vaccine is viable, it is safe to store, handle, and administer the vaccine per usual.
 If the determination report indicates the vaccine is not usable (not viable), remove from your storage unit and dispose of it according to your organization's policies, and report the wasted vaccine to WIR (see steps in the following section).

Report Wasted Vaccine in WIR

Clinics must account for all doses of vaccine. If you have wasted vaccine, you will need to modify the quantity in WIR for the respective lot number.

Step 1. Select the vaccine/lot in your inventory

Trade Name	Lot Number	Inv On Hand	Active	Public	Exp Date
JYNNEOS	FDP00003	55	Y	Y	08/31/2023

Step 2. Under **Modify Quantity On Hand**

- Select the **Reason** of “Doses Wasted”
- Select the appropriate **Waste Reason**

Modify Quantity On Hand

Action:

Amount:

Reason:

Waste Reason:

Broken Vial/Syringe

Vaccine drawn into syringe but not admin

Lost or unaccounted for vaccine

Non vaccine product (e.g. IG, HBIG, Dil)

Open vial but all doses not administered

Other

Step 3. If the **Waste Reason** is “Other” you will be provided a field **Brief Description** in which you will need to enter in the reason.

Brief Description:

Inventory in WIR Sites

- The hubs will transfer JYNNEOS vaccine to the site with the correct PIN; clinics should leave their JYNNEOS inventory in the site associated with their WIR PIN.
- Clinics should not create a “new site” within WIR for monkeypox vaccine.
- Do not transfer inventory to another existing site that does not have a PIN.
- If clinics create a “new site,” DHS loses visibility of the inventory. Those doses also won’t be accounted for reporting on statewide inventory on hand.

Vaccine Safety

Vaccine Adverse Event Reporting System

Report all adverse events to the [Vaccine Adverse Event Reporting System](#) (VAERS).

- VAERS is the nation’s passive vaccine safety surveillance program that serves as a national early warning system by helping to detect unusual or unexpected reporting patterns of adverse events for vaccines.
- VAERS is co-managed by CDC and the U.S. Food and Drug Administration (FDA). It can receive reports from anyone, including patients, parents, caregivers, and health care providers. Health care providers are required to report certain adverse events that occur after vaccination. VAERS is not designed to identify cause and effect. If an adverse event is reported to VAERS, that doesn’t mean that the vaccine caused

the adverse event. Instead, the system allows detection of potential safety concerns that might need further investigation.

- These adverse event reports are studied by vaccine safety experts who look for previously unobserved adverse events, or changes in patterns of reporting of adverse events after people receive a particular vaccine.

Contraindications

Contraindications for JYNNEOS vaccine include severe or immediate reaction to any component of the vaccine (e.g., gentamicin, ciprofloxacin, egg protein, benzonase). For complete information, please read the [package insert](#) and the [ACIP recommendations](#).

New 8/4/2022 Personal Protective Equipment in Healthcare Settings

Please review [CDC's infection prevention and control](#) webpage for information about personal protective equipment and other infection control guidance.

Important: Reducing Stigma in Monkeypox Communication

All clinic staff who interact with patients should be trained on communication techniques that reduce stigma. At minimum, please review the CDC's "[Reducing Stigma in Monkeypox Communication and Community Engagement](#)" document with your staff and provide additional training and support as needed.

JYNNEOS Vaccine Reference Table

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	Use in younger populations requires submission of a single-use Expanded Access Investigational New Drug (EA-IND) (“Compassionate Use”) application
Dosing Regimen or Schedule	2-dose vaccine series (full protection is anticipated 2 weeks following 2 nd 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.
Post-Exposure Prophylaxis (PEP)	The sooner an exposed person gets the vaccine, the better. ACIP 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	Administer by subcutaneous (SQ) injection; allow vaccine to thaw and reach room temperature before use (see package insert)
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
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