




JYNNEOS Vaccine Update

August 26, 2022

Housekeeping

- **How to Ask Questions**

- Click on the  icon found at the bottom part of your screen
- A box will open where you can type in questions, comments, indicate sound problems, etc.
- Use this throughout the webinar to ask questions

- **Slides & Recording**

- This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: [MPV Resources for Health Care Professionals \(michigan.gov\)](http://MPVResourcesforHealthCareProfessionals(michigan.gov))

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Background on Monkeypox Virus



Background on Monkeypox

- Monkeypox virus (MPV) is endemic in parts of Africa
 - More than 1,000 cases reported annually in the Democratic Republic of the Congo in recent years
 - Nigeria reported ongoing spread of monkeypox since 2017
 - When virus re-emerged after nearly 40 years with no reported cases
- Analysis by CDC experts found that there are at least two genetically distinct variants of monkeypox virus circulating in the current outbreak
 - Both of which share common ancestors of strains present in Nigeria since 2017
 - Shows it's likely that there were at least two separate instances when monkeypox virus spread from animals to people in Nigeria, then began to spread person-to-person
- Experts have yet to identify where monkeypox virus is found in nature

Background on Monkeypox, cont...

- Caused by a virus in the same family as the virus that causes smallpox
 - Typically results in milder infection
- Most infections last 2-4 weeks and resolve without specific treatment
- Monkeypox is a rare but potentially serious disease
 - Typically begins with a flu-like illness and swelling of the lymph nodes
 - May progress to include a widespread rash on face and body
- In recent cases, patients developed rashes without flu-like symptoms first
- The type of monkeypox seen in this outbreak is rarely fatal
 - More than 99% of people who get this form of the disease are likely to survive

Monkeypox Virus Symptoms



Monkeypox Symptoms

- People with monkeypox may first develop a flu-like illness with fever, headache, muscle aches, exhaustion, and enlarged lymph nodes
 - A characteristic rash, which can appear like blisters or pimples, occurs a few days later
 - In recent cases, patients developed localized rashes on or around the genitals or anus without having flu-like symptoms first
- Early flu-like symptoms of monkeypox can include:
 - Fever
 - Headache
 - Muscle aches and backache
 - Swollen lymph nodes
 - Chills
 - Exhaustion

Monkeypox Symptoms, cont...

- Sometimes, the rash is located on or near the genitals or anus
 - But may be in other areas like the hands, feet, chest, neck, or face
- The sores can look like pimples or blisters and may be painful or itchy
 - The sores typically go through several stages, including scabs, before healing
 - Sores may be inside the body, including the mouth, vagina, or anus
- Monkeypox can be spread from the time symptoms start until all sores have healed and a fresh layer of skin has formed
- The illness may last for up to 2–4 weeks and usually resolves without specific treatment



Monkeypox Virus

Health and Human Service (HHS) Response



HHS Monkeypox Response

- HHS is managing the monkeypox virus response
- JYNNEOS vaccine and TPOXX are both stored in the Strategic National Stockpile (SNS)
- Allocations and distributions are tracked in Tiberius and Health Partner Ordering Portal (HPOP)
 - Not our normal vaccine distribution system for VFC vaccines or COVID-19 vaccines
- HHS is only allowing states five distribution sites per allocation
 - Depending on states utilizing the hub and spoke model
- States should focus doses to areas with high at-risk populations (men who have sex with men [MSM]), HIV)
 - Majority of doses have gone to SE MI and SW MI

Monkeypox Virus

Michigan's Guiding Principles



Michigan's Monkeypox Guiding Principles

- To distribute vaccine rapidly in an equitable way to those at highest risk for MPV
 - Prioritizing those at risk for severe outcomes
- To value the input of the most affected community
- To communicate transparently
- To be flexible and adapt the strategy according to available data and resources

Michigan's Monkeypox General Considerations

- Monkeypox is a virus, generally spreads through close or intimate contact with people who have the infection
 - Symptoms include a rash and fever
- Many of those affected in the current global outbreaks are men who have sex with men (MSM)
 - However, anyone who has been in close contact with someone who has MPV can get the illness
- While transmission can occur from intimate contact, transmission may also occur from non-sexual contact, which includes household contact or sharing of contaminated linens
- Many of the current MPV cases in Michigan also have Sexually Transmitted Infections (STI)

Michigan's Monkeypox General Considerations, cont...

- People are considered fully vaccinated and are expected to have reached peak immunity approximately two weeks after their second shot of JYNNEOS
 - Those vaccinated should continue to take steps to protect themselves from infection
 - Avoid close, skin-to-skin contact, including intimate contact, with someone who has MPV or symptoms of MPV
- It is essential to notify named and venue- or event-associated contacts as soon as possible to be able to provide vaccination within 14 days
- CDC recommends JYNNEOS to be given within four days from date of exposure, for the best chance to prevent onset of disease
 - If given between four and 14 days after the date of exposure, vaccination may reduce the symptoms of disease but may not prevent the disease

Michigan's Monkeypox Overarching Strategy

- MDHHS's strategy aims to expand vaccination for individuals at risk
 - Vaccine will be provided through a hub and spoke model
 - Michigan's current vaccine allocation is entirely JYNNEOS vaccine
- MDHHS recognizes that current vaccine supply is limited
 - Strive to utilize all doses of vaccine as soon as available to help mitigate spread
- MDHHS encourages use of the specific vaccine strategies to rapidly deploy vaccine to those at risk of MPV
 - Prioritizing those at risk of severe disease
 - Encourage providers and LHDs to use judgement when interpreting the strategies
 - Understanding that not all decisions will be clear-cut
 - Use liberal judgment when dispensing vaccine to those at defined high-risk for MPV

Monkeypox Virus

Michigan's Specific Vaccine Strategies



Specific Vaccine Strategies to Prevent MPV

Post-Exposure Prophylaxis (PEP)

- PEP is important for controlling outbreaks and preventing further transmission
 - Vaccinate following [intermediate or high-risk exposure](#) to MPV to prevent illness
 - It is important to identify contacts of confirmed or probable MPV cases to offer vaccine for PEP and to monitor for early signs of illness
 - This includes household, sexual, and other close contacts
 - Use vaccine for outbreak response to those linked to an outbreak or a diagnosed case with exposure within the last 14 days

[Michigan monkeypox \(MPV\) vaccine administration considerations for local health departments \(LHDs\) and health care providers](#)

Specific Vaccine Strategies to Prevent MPV, cont...

Expanded Post-Exposure Prophylaxis (PEP)++

- PEP++ aims to reach recently exposed persons or persons at high-risk for vaccination
- When combined with other mitigation measures, PEP++ may slow the spread of disease in areas with large numbers of MPV cases
 - This would suggest a higher level of MPV transmission
- PEP++ strategies should include:
 - Collaboration with trusted community providers
 - Creative marketing
 - Outreach strategies to the most at-risk populations

[Michigan monkeypox \(MPV\) vaccine administration considerations for local health departments \(LHDs\) and health care providers](#)

Specific Vaccine Strategies to Prevent MPV, cont...

Utilize Expanded Post-Exposure Prophylaxis (PEP++) in the Following Situations

- Individuals engaged in any type of sex work
- Partners of individuals who engage in higher-risk sexual activities
- Close/household contacts of individuals who have been exposed to MPV or engaged in higher-risk activities
- Men who have sex with men and have a history of STIs in the last year
- Individuals who plan to have multiple sex partners
- Individuals who plan to have close contact at a high-risk event or high-risk venue
- Individuals taking HIV PreP or those living with HIV

Consider ring vaccination strategies associated with events or venues (vaccinating contacts of contacts).

Specific Vaccine Strategies to Prevent MPV, cont...

Pre-Exposure Prophylaxis (PrEP)

- PrEP is administering doses of vaccine before the individual is likely to have an exposure to MPV
 - Especially in areas with no reported local transmission
- The following groups may be considered for PrEP at this time:
 - Lab workers performing testing for orthopoxviruses (not collecting or packaging specimens)
 - Anyone residing/working in a congregate setting (e.g., dorm, prison, long term care facility) at risk for an outbreak
 - Anyone using/working in a facility (e.g., sports team, fitness center, classroom) at risk for an outbreak
 - Individuals requesting vaccine with risk assessment conducted by LHD/clinicians
 - Based on available data, broadly available PrEP will be offered in the future

[Michigan monkeypox \(MPV\) vaccine administration considerations for local health departments \(LHDs\) and health care providers](#)

Monkeypox Virus

JYNNEOS Vaccine

Providers and Hubs



JYNNEOS Vaccine Hub/Provider Expectations

- JYNNEOS vaccine is a scarce resource
- MDHHS uses vaccine hubs (mostly local health departments)
 - MDHHS places the order for JYNNEOS vaccine to be delivered to one of the hubs—can't order in MCIR
- Monkeypox Provider Agreement
 - Providers must be enrolled in MCIR and have access to the Outbreak Inventory
 - JYNNEOS vaccine providers must be accountable for JYNNEOS vaccine in MCIR
 - Upon receiving JYNNEOS vaccine vials, **must** manually enter vials in the MCIR Outbreak Inventory
 - To ensure proper inventory management JYNNEOS vaccine providers must balance the JYNNEOS inventory daily



The U.S. Department of Health and Human Services (HHS) and its components the Administration for Strategic Preparedness & Response (ASPR), Strategic National Stockpile (SNS), and the Centers for Disease Control and Prevention (CDC) greatly appreciate your organization's participation in the HHS Monkeypox Vaccination Program.¹ With use of the JYNNEOSTM or ACAM2000[®] vaccine provided at no cost by the US government (this vaccine), the provider and provider's organization (Organization) will be deemed to have agreed to comply with the requirements of this Agreement. Any person accessing this vaccine is subject to compliance with the terms of this Agreement, including any updates to the Agreement as noted in paragraph 3.

This vaccine remains the property of the U.S. Government.

Undergoing Edits for Michigan Specific Guidance

1. Organization must administer JYNNEOS or ACAM2000 in accordance with all relevant requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP)² (including those in the CDC Interim Clinical Considerations for Monkeypox Vaccination³ and any CDC Emergency Use Instructions⁴ as they may be revised from time to time), and consistent with the scope of the Food and Drug Administration's (FDA's) approval, authorization, and/or any applicable expanded access requirements per FDA's protocol.⁵
2. This Agreement expressly incorporates all information included in weblinks in this Agreement as they may be revised from time to time. HHS reserves the right to update this Agreement at any time by posting updates on the HHS Monkeypox Vaccination Program Provider Agreement update webpage at: <https://www.cdc.gov/poxvirus/monkeypox/provider-agreement.html>. Organization must monitor this website for updates and comply with any such posted updates.
3. Organization must record the following Vaccine Administration Data elements in each vaccine recipient's record:
 - a. Administration address (including Company)*
 - b. Recipient name and ID*
 - c. Recipient date of birth*

Monkeypox Virus

JYNNEOS Vaccine

Guidance



Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak

Updated August 22, 2022

[Print](#)

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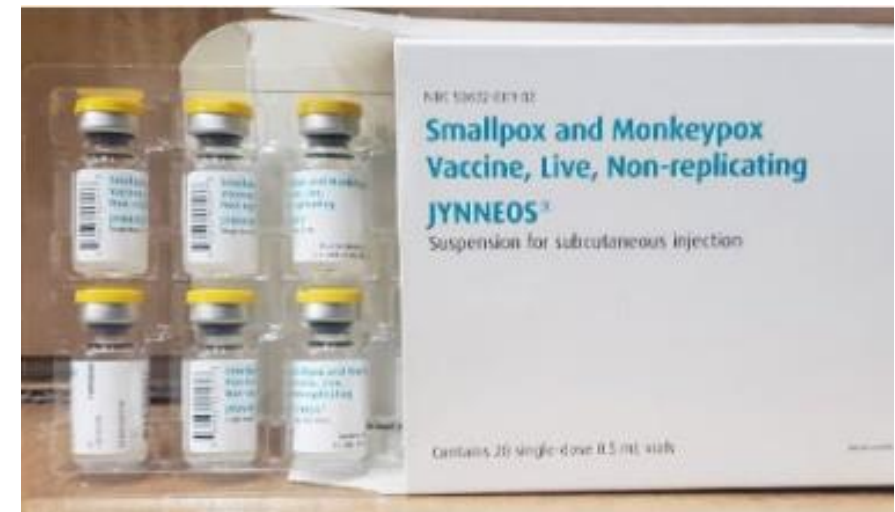
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Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

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 Intradermal Background

- 1/5 of the dose (0.1 mL) given ID on the same schedule produces similar efficacy to Subcut
 - More local redness and itching, less local pain noted
- Could facilitate vaccination of entire current target population and allow for additional supply in the event of further spread



Michigan's JYNNEOS Vaccine Guidance

- MDHHS recognizes current vaccine supply is limited
 - Strive to utilize all doses of vaccine as soon as they become available
- MDHHS recommends that providers switch to intradermal (ID) administration as soon as possible for use with all eligible patients when indicated
- The expectation is ID route is the preferred route to extend the amount of vaccine for response
- We understand there will be situations when Subcut route will be used
- MDHHS recommends that any individual who receives JYNNEOS vaccine, complete the vaccine series by receiving a second dose 28 days after the first

[JYNNEOS Vaccine Clinical Considerations](#)

Monkeypox Virus

JYNNEOS Vaccine

Preparation and Administration



Standard Regimen—JYNNEOS Subcutaneous (Subcut, SC)

- Age Indications
 - People under 18 years of age and people 18 years of age and older who have a history of developing keloid scars
- Subcut 0.5 mL injection into the fatty tissue
 - Over the triceps area in the upper arm
 - Anterolateral thigh for younger than 12 months
- CDC offers a short training [video about subcutaneous vaccine administration](#)
- Please refer to the Preparation & Administration Summary for Special Populations

[JYNNEOS Subcut Vaccine Preparation and Administration](#)

MONKEYPOX

Adults with Certain Medical Conditions and Children

JYNNEOS Smallpox and Monkeypox Vaccine

Subcutaneous Vaccine Preparation and Administration Summary: **STANDARD REGIMEN**

General Information

Vaccine: JYNNEOS Smallpox and Monkeypox vaccine
Single-dose vial
Diluent: None
Dosage: 0.5 mL

Age Indications

People 18 years of age and older who have a history of keloid scars, and all people younger than 18 years of age.

Vaccination Schedule

Administer two doses of JYNNEOS (0.5 mL each)
28 days apart

- For more details on the dosing interval, refer to www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html.

Administration

Subcutaneous (subcut) injection into the fatty tissue over the triceps area in the upper arm, or in the anterolateral thigh for infants younger than 12 months of age

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.
 - » **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.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date (BUD) labels to track storage times.

Prepare and Administer the Vaccine

1. Assess recipient status:
 - » Screen for contraindications and precautions.
 - » Review vaccination history.
 - » Review medical considerations.
2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if used), and any time hands become soiled.
3. Frozen vaccine must be thawed for 10 minutes before using.
4. 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.
5. With the vial upright, gently swirl the vaccine for 30 seconds.
6. 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.
7. Using a new, sterile alcohol prep pad, cleanse the stopper of the vaccine vial.
8. Choose the correct equipment for subcutaneous injection: use sterile syringe with a 23-25 gauge, 5/8" needle. **Always use a new, sterile needle and syringe for each injection.**
9. Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

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Alternative Regimen—JYNNEOS Intradermal (ID)

Preferred

- Age Indications
 - People 18 years of age and older who do not have a history of keloid scars
- ID 0.1 mL injection into the volar aspect (inner side) 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
- Should produce a noticeable pale elevation of the skin (wheal)

[JYNNEOS ID Vaccine Preparation and Administration](#)

MONKEYPOX

Adults in the General Population
JYNNEOS Smallpox and Monkeypox Vaccine
Intradermal Vaccine Preparation and Administration Summary: **ALTERNATIVE DOSING REGIMEN**

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/poxvirus/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.

Prepare and Administer the Vaccine

1. Assess recipient status:
 - Screen for contraindications and precautions.
 - Review vaccination history.
 - Review medical considerations.
2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves, and any time hands become soiled.
3. Frozen vaccine must be thawed for 10 minutes before using.
4. 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.
5. With the vial upright, gently swirl the vaccine for 30 seconds.
6. 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.
7. Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.
8. 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.**
9. Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

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JYNNEOS Intradermal Vaccination Preparation

- With vial upright, gently swirl for 30 seconds before withdrawing the dose
- Examine the vaccine
 - 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 vaccine vial
- Choose correct equipment for intradermal injection:
 - 26 or 27 gauge, 3/8", 1/4" to 1/2" needle with a short bevel
- Withdraw correct dosage (0.1 mL) out of a 0.5 mL single dose vial
- Do **NOT** combine residual vaccine from multiple vials to obtain a dose
- For new vials: note the date and time the vial was first punctured—once punctured, **must** discard it after 8 hours
- Immediately replace the vaccine vial in the refrigerator between doses—do not pre-fill syringes

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.



CS 333451 08/09/2022

www.cdc.gov/monkeypox

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



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.



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www.cdc.gov/monkeypox

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 3

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



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www.cdc.gov/monkeypox

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 4

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.



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www.cdc.gov/monkeypox

Video on Administering JYNNEOS Intradermally

MONKEYPOX

How to administer
a JYNNEOS vaccine
intradermally.



VIDEO

How to administer a JYNNEOS vaccine intradermally

Video Length: 00:00:55

[Watch Video](#)

Interchangeability

- Persons aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcut regimen
 - May receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series

Monkeypox Virus

Adverse Event Reporting

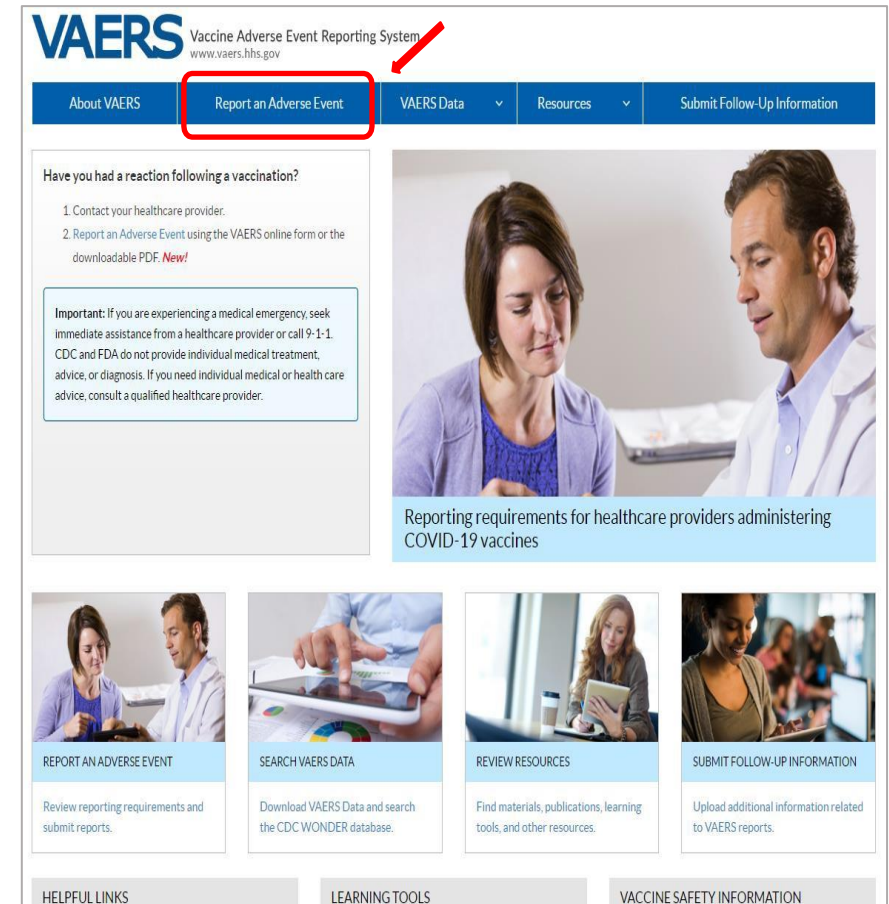


Safety

- Contraindications and precautions
 - People presenting with minor illnesses, such as a cold, may be vaccinated
 - People who are moderately or severely ill should wait until they have recovered to their baseline state of health before vaccination
- When vaccinating should consider observing patients for 15 minutes after vaccination to decrease the risk for injury should they faint
 - If syncope develops, patients should be observed until the symptoms resolve

Reporting to VAERS

- When administering JYNNEOS under the EUA providers are **required** to report the following adverse events that occur after JYNNEOS vaccination:
 - Vaccine administration errors whether or not associated with an adverse event
 - Serious adverse events (irrespective of attribution to vaccination)
 - Cases of cardiac events including myocarditis and pericarditis
 - Cases of thromboembolic events and neurovascular event
 - Information on how to submit a report to VAERS is available at <https://vaers.hhs.gov> or by calling 1-800-822-7967.



Monkeypox Virus

JYNNEOS Vaccine

Storage and Handling



Indication for Use	Standard regimen (subcutaneous): <ul style="list-style-type: none"> • People under 18 years of age • People of any age with history of keloid scarring 	Alternative regimen (intradermal): <ul style="list-style-type: none"> • People 18 years and older
Number of Doses in Series	2 doses	2 doses
Interval Between Doses	28 days	28 days
Preparation of Vaccine	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use. ^{3,4}	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use. ^{3,4}
Administration	Subcutaneous (Subcut) Injection⁵ (standard regimen) preferably into the anterolateral thigh for infants less than 1 year of age, or into the upper arm (fatty tissue over triceps) for individuals 1 through 17 years of age.	Intradermal (ID) Injection⁶ (alternative regimen) volar aspect (inner side) of the forearm.
Reconstitution	DO NOT DILUTE	DO NOT DILUTE
Dosing Volume	0.5 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows one dose per vial).	0.1 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows up to five doses per vial).
Storage Time in Syringe	Draw vaccine up right before use - DO NOT PRE-DRAW.	Draw vaccine up right before use - DO NOT PRE-DRAW.
Storage Requirements in Freezer* -25°C to -15°C (-13°F to +5°F) ³	Expiration: on carton label ⁷ / look up ⁸	Expiration: on carton label ⁷ / look up ⁸
Storage Requirements in Refrigerator (DO NOT REFREEZE)* +2°C to +8°C (+36°F to +46°F) ³	Unpunctured Vial: Expiration 8 weeks Beyond Use Date(BUD). ^{4,7}	Unpunctured Vial: Expiration 8 weeks Beyond Use Date(BUD). ^{4,7}
	Punctured Vial: DO NOT PRE-DRAW, must discard within 8 hours of puncture/vial cap removal. ³	Punctured Vial: DO NOT PRE-DRAW, must discard within 8 hours of the first puncture. ³ (refrigerate after each use)

***Important note:** All vaccine, whether received refrigerated or frozen, is originally frozen from the manufacturer. If you receive refrigerated vaccine, it is thawed vaccine. Do NOT refreeze, store it in the refrigerator. Thawing.


www.michigan.gov/monkeypox

Storage of JYNNEOS

- Refrigerator storage between 2°C and 8°C (between 36°F and 46°F)
 - Refrigerated vaccine is thawed vaccine and must be used within 8 weeks from thawing
 - DO NOT refreeze
- If vaccine is received frozen and requires storage before use, maintain:
 - Freezer storage between -25°C and -15°C (between -13°F and +5°F)
 - If storing vaccine that was received frozen in the freezer, the vaccine should be used within the printed expiration date on the carton

[Monkeypox Vaccine Storage and Handling Summary](#)


MONKEYPOX




Monkeypox Vaccine

Storage and Handling Summary


Storage Basics



Store vaccine preferably in a purpose-built refrigerator or freezer.



Use a digital data logger to monitor temperature of the storage unit.



Check and record storage unit temperatures daily.

What to do when vaccine is received

- Unpack vaccine immediately upon arrival at the clinic.
- Check the cold chain monitor, a device used to monitor vaccine temperatures during transport, for any indication of a temperature excursion during transit.
- Check the expiration date on the carton.
- Store vaccine in the original package in order to protect from light.

Important note: All vaccine, whether received refrigerated or frozen, is originally frozen from the manufacturer. If you receive refrigerated vaccine, it is thawed vaccine. Do NOT refreeze. Thawed vaccine must be used within 8 weeks from thawing.

Vaccine Storage

If vaccine is received refrigerated and requires storage before use, maintain:

- Refrigerator storage between 2°C and 8°C (between 36°F and 46°F).
- As specified in the note above, refrigerated vaccine is thawed vaccine and must be used within 8 weeks from thawing.
- DO NOT refreeze.

If vaccine is received frozen and requires storage before use, maintain:

- Freezer storage between -25°C and -15°C (between -13°F and +5°F), if freezer capacity is available, **OR** refrigerator storage between 2°C and 8°C (between 36°F and 46°F).
 - If storing vaccine that was received frozen **in the freezer**, the vaccine should be used within the printed expiration date on the carton. Please note that the expiration date is not shown on the individual vial. Expiration date by lot number can be found at <https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx>.
 - If storing vaccine that was received frozen **in the refrigerator**, it is thawed vaccine and must be used within 8 weeks from thawing. DO NOT refreeze once thawed. It takes about 10 minutes to thaw from -20°C (-4°F).

JYNNEOS may be stored refrigerated between 2°C and 8°C (between 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 Beyond Use Date (BUD) guidance differs from the package insert guidance, 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).

Monkeypox Virus

JYNNEOS Vaccine

Resources



MPV Resources for Health Care Professionals

MDHHS > Keeping Michigan Healthy > Communicable & Chronic Diseases > Communicable Diseases & Immunization > MPV > For Health Providers

Handout for those exposed – give to confirmed MPV cases to share with close contacts

- [Let's Talk Monkeypox Handout](#)
- [Let's Talk Monkeypox Handout \(Arabic\)](#)
- [Let's Talk Monkeypox Handout \(Spanish\)](#)

[MDHHS Communicable Disease Information and Resources](#)

[Information for Veterinarians](#)

[Michigan's Monkeypox Vaccine Strategy - Information for HCP](#)

For more information or for questions, please contact your [local health department](#). If you need additional information, contact MDHHS Communicable Disease at 517-335-8165.

Press Releases

[MDHHS announces first probable monkeypox case in Michigan](#)

Clinical Guidance

[Monkeypox Treatment Information](#)

[June 2022 CDC Webinar Slides on What Clinicians Need to Know](#)

[CDC Updates about Clinical Diagnosis and Treatment](#)

[Considerations for Monkeypox Vaccination](#)

[JYNNEOS Intradermal Injection Final](#)

[JYNNEOS Operational Guide 8-12-22](#)

[JYNNEOS Vaccine Resource Guide](#)

[TPOXX Request Procedure](#)

Webinars

MDHHS Monkeypox Guidance and Education Website

www.michigan.gov/monkeypox

More Key CDC Guidance

[JYNNEOS Standing Orders \(Standard Regimen\) \[233 KB, 3 pages\]](#)

[JYNNEOS Standing Orders \(Alternative Regimen\) \[243 KB, 3 page\]](#)

Additional MDHHS JYNNEOS Guidance

JYNNEOS¹ Vaccine Resource Guide Smallpox and Monkeypox Vaccine

Indication for Use	Standard regimen (subcutaneous):	Alternative regimen (intradermal):
	<ul style="list-style-type: none"> People under 18 years of age People of any age with history of keloid scarring 	<ul style="list-style-type: none"> People 18 years and older
Number of Doses in Series	2 doses	2 doses
Interval Between Doses	28 days	28 days
Preparation of Vaccine	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use. ^{3,4}	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use. ^{3,4}
Administration	Subcutaneous (Subcut) Injection⁵ (standard regimen) preferably into the anterolateral thigh for infants less than 1 year of age, or into the upper arm (fatty tissue over triceps) for individuals 1 through 17 years of age.	Intradermal (ID) Injection⁶ (alternative regimen) volar aspect (inner side) of the forearm.
Reconstitution	DO NOT DILUTE	DO NOT DILUTE
Dosing Volume	0.5 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows one dose per vial).	0.1 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows up to five doses per vial).
Storage Time in Syringe	Draw vaccine up right before use - DO NOT PRE-DRAW.	Draw vaccine up right before use - DO NOT PRE-DRAW.
Storage Requirements in Freezer* -25°C to -15°C (-13°F to +5°F) ³	Expiration: on carton label ⁷ /look up ⁸	Expiration: on carton label ⁷ /look up ⁸
Storage Requirements in Refrigerator (DO NOT REFREEZE)* +2°C to +8°C (+36°F to +46°F) ³	Unpunctured Vial: Expiration 8 weeks Beyond Use Date(BUD). ^{4,7} Punctured Vial: DO NOT PRE-DRAW, must discard within 8 hours of puncture/vial cap removal. ³	Unpunctured Vial: Expiration 8 weeks Beyond Use Date(BUD). ^{4,7} Punctured Vial: DO NOT PRE-DRAW, must discard within 8 hours of the first puncture. ³ (refrigerate after each use)

*Important note: All vaccine, whether received refrigerated or frozen, is originally frozen from the manufacturer. If you receive refrigerated vaccine, it is thawed vaccine. Do NOT refreeze, store it in the refrigerator. Thawed vaccine must be used within eight weeks (BUD) from thawing.

¹Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC

²Vaccination Administration Considerations for Specific Populations | Monkeypox | Poxvirus | CDC

³Fact Sheet for Healthcare Providers for JYNNEOS

⁴JYNNEOS Smallpox and Monkeypox Vaccine Storage and Handling Summary (cdc.gov)

⁵How to administer intramuscular and subcutaneous vaccine injections (immunize.org)

⁶How to administer a JYNNEOS vaccine intradermally (video)

⁷MVA-BN Information Letter (hhs.gov)

⁸Monkeypox (hhs.gov)

Michigan Department of Health and Human Services-Division of Immunization
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Revised 8-19-22

JYNNEOS Vaccine Operational Guide

This operations guide is to ensure providers administering JYNNEOS vaccine are prepared to properly store, handle, and administer intradermal or subcutaneous injections. JYNNEOS providers should use this checklist as a comprehensive overview to support vaccination efforts and confirm compliance with requirements expected. Completion of this checklist is **REQUIRED prior to performing JYNNEOS vaccination. Storage and handling, along with administration guidance are required to be followed on a daily basis.**

Instructions: This is intended to be used as an electronic checklist, allowing direct links to resources. These resources can also be found at www.michigan.gov/mpv. Bookmark this website for support and frequent updates.

MCIR SITE REGISTRATION, USER ACCESS, MCIR DATA ENTRY PREPARATION

<input type="checkbox"/>	Providers must be registered in MCIR before administering JYNNEOS vaccine. For more information on how to register visit the Provider Site Usage Agreement . Provider must have access to the MCIR Outbreak Module.
<input type="checkbox"/>	Ensure MCIR user access for individuals at your facility who may administer vaccine or look up records. <ul style="list-style-type: none"> These requests for access are performed by the MCIR Site Administrator at your facility. To request user access, associate users, etc., view tip sheets, and videos, the Site Administrator Manual is available here. If you do not know who your Site Administrator is, contact your MCIR Regional staff.
<input type="checkbox"/>	Establish a process for the documentation of JYNNEOS vaccine administration into your clinic's medical record systems and MCIR within 24 hours. (e.g., HL7 VXU from EHR, Upload to MCIR, Direct Data Entry into MCIR).
<input type="checkbox"/>	Work with Regional MCIR staff for assistance and training on MCIR.

MONKEYPOX



How to administer a JYNNEOS vaccine intradermally.



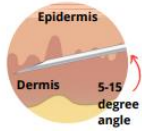
Step 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.



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.



Step 3

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



Step 4

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.

[Watch a video demonstration from the CDC.](#)

[View the JYNNEOS Vaccine Clinical Considerations.](#)

For more information visit, Michigan.gov/MPV.

[MDHHS MPV Resources for Health Care Professionals](#)

Vaccine Information Statements (VIS)

ENGLISH

FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT JYNNEOS (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON-REPLICATING) TO PREVENT MONKEYPOX DISEASE IN INDIVIDUALS DETERMINED TO BE AT HIGH RISK FOR MONKEYPOX INFECTION

You or your child is being offered JYNNEOS to prevent monkeypox disease. This Fact Sheet contains information to help you understand the risks and benefits of receiving JYNNEOS, which you or your child may receive because there is an outbreak of monkeypox.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to:

- Allow use of JYNNEOS given between layers of the skin for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection; and
- Allow use of JYNNEOS given beneath the skin for prevention of monkeypox disease to individuals younger than 18 years of age determined to be at high risk for monkeypox infection.

For more details about an EUA please see "What is an Emergency Use Authorization?" at the end of this document. JYNNEOS is not approved for use in individuals under 18 years of age in the United States. For individuals 18 years of age and older, JYNNEOS given between layers of skin (intradermally) is not approved in the United States. Read this Fact Sheet for information about JYNNEOS. Talk to your healthcare provider about your options or if you have any questions. Under the EUA, there is an option to accept or refuse JYNNEOS.

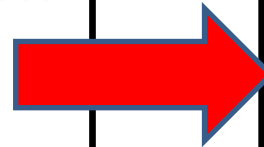
WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS MONKEYPOX?

Monkeypox is a disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as the virus that causes smallpox. Monkeypox symptoms are similar to smallpox symptoms, but milder, and monkeypox is rarely fatal. The monkeypox virus can spread to anyone through close skin-to-skin contact. It can also spread through touching objects, fabrics, and surfaces that have been used by someone with monkeypox or by contact with respiratory secretions. People with monkeypox get a rash that may be located anywhere on the body. The rash will go through several stages, including scabs, before healing. The rash can initially look like pimples or blisters and may be painful or itchy. Other symptoms of monkeypox can include:

- Fever
- Chills
- Swollen lymph nodes

throat, nasal congestion, or cough



COVID-19 Vaccine Specific Information - Resources

- [Pfizer](#)
- [Moderna](#)
- [Janssen \(Johnson & Johnson\)](#)

What Is New

- [Smallpox/Monkeypox VIS](#) 8-23-22
- [Jynneos EUA Fact Sheet Recipients Caregivers](#) 8-9-22
- [Jynneos Healthcare Provider Fact Sheet](#) 8-9-22
- [Ebola VIS](#) 6-30-22
- [Rabies VIS](#) 6-2-22
- [Pneumococcal Conjugate \(PCV13, PCV15\)](#)
- [Zoster/Shingles Recombinant \(RZV\) VIS](#)
- [Dengue VIS](#) 12-17-21

JYNNEOS EUA Fact Sheets and
Smallpox/Monkeypox VIS
www.michigan.gov/vis

Thank You!

Next “Noontime Knowledge”
Update: TBD

Please watch your email for an
updated link and topic!

Questions Email: [MDHHS-MPV-
Vaccine@michigan.gov](mailto:MDHHS-MPV-Vaccine@michigan.gov)

www.Michigan.gov/monkeypox

