

WEST VIRGINIA MONKEYPOX VACCINE STRATEGY

Background

The Centers for Disease Control and Prevention (CDC) is tracking multiple cases of monkeypox across the United States. Current evidence suggests community transmission is contributing to the outbreak and early data indicates that gay, bisexual, and other men who have sex with men make up a majority of reported cases. The U.S. Department of Health and Human Services (HHS) announced a nationwide vaccine strategy to mitigate the spread of monkeypox. This strategy includes vaccination and protection for those at-risk of monkeypox and prioritization of vaccines for areas with the highest number of cases. Under the strategy, HHS is rapidly expanding the access to the JYNNEOS vaccine product for prophylactic use against monkeypox using a tiered distribution system.

Although production levels for the vaccine are increasing, supply is currently low across the United States. Eligibility for monkeypox vaccination may change as the outbreak evolves and based on vaccine supply. HHS has allocated jurisdictions of the JYNNEOS vaccine from the Strategic National Stockpile (SNS) under the National Monkeypox Vaccine Strategy.

Under Phase 1 Allocation, West Virginia was authorized 0 vials on June 29, 2022.

Under Phase 2a Allocation, West Virginia was authorized 237 vials on July 9, 2022.

Under Phase 2b Allocation, West Virginia was authorized 190 vials on July 15, 2022.

Under Phase 3 Allocation, West Virginia was authorized 600 vials on July 28, 2022.

Allocations are based on two factors: The current jurisdictional case count and the estimated size of the underlying population in the jurisdiction who might benefit from expanded vaccination at this point in the outbreak. This underlying population includes gay, bisexual, and other men who have sex with men with HIV or who are eligible for HIV pre-exposure prophylaxis (HIV PrEP); this data can be accessed at <https://www.cdc.gov/nchhstp/atlas/index.htm>.

There is no data currently available on the clinical efficacy or effectiveness of JYNNEOS vaccine in the monkeypox outbreak. Due to these limitations, individuals who receive the JYNNEOS vaccine should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.

Vaccine Strategies to Prevent Monkeypox

1. **Post-Exposure Prophylaxis (PEP):** Local health departments with probable or confirmed cases of monkeypox may issue standard PEP for individuals who have been where the degree of exposure was determined to be **HIGH** by completing the [monkeypox close contact investigation questionnaire](#) or [healthcare exposure risk assessment questionnaire](#).
 - a) JYNNEOS vaccine should be given within 4 days from the date of exposure for the best chance to prevent onset of the disease. If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.
2. **Pre-exposure Prophylaxis (PrEP):** Local health departments may designate 1-2 response team members to be vaccinated for preparedness purposes in alignment with recommendations from the [Advisory Committee of Immunization Practices](#). Other eligible occupations for PrEP include research laboratory personnel working with orthopoxviruses and clinical laboratory personnel performing diagnostic testing for orthopoxviruses.

- a) PrEP is not requirement or recommendation when giving JYNNEOS to exposed contacts (no matter the risk determination) as the vaccine is a replication-deficient virus and there is no risk for inadvertent autoinoculation.
3. **Expanded Post-exposure Prophylaxis (PEP++):** Individuals with certain risk factors may be considered for PEP++. This approach aims to reach the population at highest risk, even if they have not had documented exposure to someone with confirmed monkeypox. Eligibility for monkeypox vaccination may change as the outbreak evolves or based on vaccine supply. Local health departments may administer JYNNEOS vaccine as part of a PEP++ strategy to individuals who meet the following conditions:
 - a) Gay, bisexual, or other men who have sex with men, and/or transgender, gender non-conforming, or gender non-binary; AND
 - b) Have had multiple or anonymous sex partners in the last 14 days.

Note: Individuals who have a condition that may increase their risk for severe disease if infected with monkeypox, such as HIV or another condition that weakens their immune system, or atopic dermatitis or eczema, should especially consider getting vaccinated.

Vaccine Distribution

The JYNNEOS vaccine is available through local health departments. When a jurisdiction has exhausted 50% of their allocation, they may request additional vaccine by emailing snsvaccinerequest@wv.gov. Local health departments will need to have submitted completed copies of the Monkeypox Vaccine Administration Form provided in this guide for each person vaccinated before additional doses are approved.

Inventory Management

The JYNNEOS doses, lot, and expiration information must be manually entered as inventory in West Virginia Statewide Immunization Information System (WVSIS) upon receipt. Providers must choose the eligibility category of Public ('PUB') to have doses administered to patients automatically deduct from inventory in WVSIS. Providers must track all vaccines given and any doses wasted by lot number and reason (temperature too cold/hot, dropped vial, expired) and report this information to WVSIS.

When manually entering vaccines, providers must first conduct a search to ensure vaccine is currently not in their inventory.

To manually enter vaccines into WVSIS:

1. Log into **WVSIS**.
2. Select your **Organization**.
3. Select your **Facility**.
4. Click the **Lot Numbers** blue tab.
5. Click **Search/Add**.
 - i) You are taken to the **Lot Number Maintenance** screen.
6. Select the below items in the drop down lists:
 - i) **Vaccine** -> **Vaccinia, smallpox monkey vaccine live, PF**
 - ii) **Manufacturer** -> **Bavarian Nordic A/S-BN**
 - iii) **Lot Number** -> Listed on the box

7. Click **Search**.
 - i) The **Search Results** will appear at the bottom of the screen. There should be no results.
8. To add the vaccine, click the **Add** button.
 - i) You are taken to the **Lot Number Maintenance [Add]** screen.
9. Enter the required fields, indicated in red.
 - i) Enter the **Expiration Date**.
 - ii) Funding Source is '**PUB**'.
 - iii) Select a of **Reasons for Change**.
 - iv) Enter the **Number of Doses Added**.
 - (a) ENTER NUMBER OF DOSES NOT VIALS.
 - (b) Since intradermal is currently the required mode of vaccine administration, providers should consider each vial to be 5 doses. For example, if you receive two vials of JYNNEOS, you should enter this as doses 10 in your inventory.
 - v) Select the **Product** -> MONKEYPOX (JYNNEOS) SDV 1-pack
 - vi) Select the **NDC Code** -> 50632-0001-01
10. Click **Add**.
 - i) The Monkeypox vaccine is now entered in your inventory.

Vaccine Storage and Handling

- The vaccine comes in single dose vials.
- Keep frozen at -25°C to -15°C (-13°F to +5°F) until expiration date.
- DO NOT store on dry ice or below -50°C (-58°F).
- JYNNEOS is shipped at -20°C and can be used through the labeled expiration date when stored between -15°C and -25°C.
- When stored at refrigerated temperatures (2°C to 8°C), unopened vials can be used for up to 8 weeks (this differs from the package insert).
- Expiration dates are printed on the carton, but not the vial. Expiration dates, along with the corresponding lot and NDC numbers can be found at <https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx>
- Store the vaccine in the original package to protect from light if vials are received in a carton; if loose vial(s) are received, please store/wrap them in material that protects them from light.
- Do not re-freeze a vial once it has been thawed.
- A digital data logger (DDL) must be used to monitor the temperature of vaccines at all times during storage and transport.

Vaccine Redistribution

When redistributing vaccine to other providers, [standard transportation guidance](#) must be followed.

- Ensure continued temperature monitoring via digital data loggers.
- Complete the appropriate [transport tracking sheet](#), including [temperatures](#) during transport. Providers must complete the tracking sheets and maintain for these records for a minimum of 3 years.
- The releasing provider must track date and time of redistribution, receiving provider info, lot number, expiration date, and number of doses redistributed. This information must be supplied

to West Virginia Department of Health and Human Resources, Division of Immunization Services (WVDIS) upon request for vaccine accountability.

- Receiving and sending providers must maintain accurate inventory in WVSIS for improved tracking.

Use of JYNNEOS

The standard regimen for JYNNEOS involves subcutaneous route of administration with an injection volume of 0.5mL, as 2 doses 4 weeks apart (28 days). In the context of the national [Public Health Emergency](#) announced August 4, 2022, an alternative regimen for individuals 18 years of age and older involves an intradermal (ID) administration with an injection volume of 0.1mL as 2 doses 4 weeks apart (28 days) be used under an [Emergency Use Authorization \(EUA\)](#).

Additional Considerations:

- The immune response takes 2 weeks after the 2nd dose for maximum development.
- When necessary, a person aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcutaneous regimen may receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series. For example, a person who received only one dose of the standard regimen before the date of initial Emergency Use Authorization for the alternative regimen (August 9, 2022), may receive one dose with the alternative regimen to complete the series. Also, a person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.
- After natural infection with monkeypox individuals are considered to have lifelong immunity and are not eligible for vaccine.
- Persons exposed to monkeypox virus and who have not received the smallpox vaccine within the last 3 years should consider getting vaccinated.

INTRADERMAL INJECTION:

1. Indication: Persons 18 years of age and older who do not have a history of keloid scars.
2. Administer two doses of JYNNEOS (0.1mL each) 28 days apart intradermal (ID) injection into the volar surface of the forearm.
3. When thawing directly from the freezer, use vaccine before date marked on the carton. For unpunctured vials stored in the refrigerator, use before beyond-use date (BUD) of 8 weeks from thawing. **Punctured vials must be kept refrigerated and discarded 8 hours after puncture.**
4. Review the [JYNNEOS Intradermal Vaccine Preparation and Administration Summary](#) prior to administering vaccine.
 - [JYNNEOS Fact Sheet for Healthcare Providers](#) should be reviewed prior to administering vaccine.
 - [JYNNEOS Fact Sheet for Recipients and Caregivers](#) should be provided to patients and caregivers prior to vaccine administration.

SUBCUTANEOUS INJECTION:

1. Age Indication: Persons 18 years of age or older who have a history of keloid scars OR persons younger than 18 years of age.
2. Administer two doses of JYNNEOS 28 day apart. Subcutaneous injection into the fatty tissue over the triceps area in the upper arm (0.5 mL each) 28 days apart.

3. When thawing directly from the freezer, use vaccine before date marked on the carton. For unpunctured vials stored in the refrigerator, use before beyond-use date (BUD) of 8 weeks from thawing. **Punctured vials must be discarded 8 hours after puncture.**
4. Review [Subcutaneous Vaccine Preparation and Administration Summary](#) prior to administering vaccine.
 - [JYNNEOS Fact Sheet for Healthcare Providers](#) should be reviewed prior to administering vaccine.
 - [JYNNEOS Factsheet for Recipients and Caregivers](#) should be provided to patients and caregivers prior to vaccine administration.



West Virginia Department of Health and Human Resources Monkeypox Vaccine Administration Form

Email completed form to the vaccine team for each vial opened to snsvaccinerequest@wv.gov
This form must be filled out in its entirety to receive additional vaccine

Screening of eligibility must take place with each immunization. I certify that the history given meets the following criteria for which I am administering the Monkeypox Vaccine (JYNNEOS):

Expanded Post Exposure Prophylaxis (PEP++)

- Gay, bisexual, or other man with has sex with men, and/or transgender, gender non-conforming, or gender non-binary; AND
- Have had multiple or anonymous sex partners in the last 14 days.

OR

Post Exposure Prophylaxis (PEP)

- Have had known exposure to a probable or confirmed monkeypox case within the past 14 days.

OR

Pre-Exposure Prophylaxis (PrEP)

- Research laboratory personnel working with orthopoxviruses, clinical laboratory personnel performing diagnostic testing for orthopoxviruses, and designated local health department staff

Date vial was opened: _____

First Name	Last Name	Lot Number	Expiration Date	Eligibility Criteria			Administration/Dose
				PEP	PEP++	PrEP	

Total vials left at your facility: _____

The vaccine is stable until it's expiration date if frozen, it is good for 8 weeks at refrigerated temperature and **once opened it is good for 8 hours and should be refrigerated between doses.**
 Please report all wasted doses in the "First Name" column as "Waste" and properly dispose of unused portions after the 8-hour period.
Do not refreeze.

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