

JYNNEOS: Mpox Vaccine Guidance

Background

Eligibility for Mpox vaccination may change based on vaccine supply and localized outbreaks. Allocations are based on the current jurisdictional case count and the estimated size of the underlying population in the jurisdiction who might benefit from expanded vaccination. This underlying population includes gay, bisexual, or other men who have sex with men (GBMSM) with a priority for people living with HIV and/or those who are eligible for HIV pre-exposure prophylaxis (HIV PrEP). Health disparities by race and ethnicity should also be considered, due to the disproportionate number of cases among people who are Black and/or Hispanic.

Recent studies from the 2022 U.S. Mpox Outbreak have estimated that the effectiveness of the JYNNEOS vaccine in preventing Mpox disease was 35-75% after one dose and 66-85% after two doses. Therefore, two doses of vaccine are recommended for better protection. For those that do develop Mpox infection after vaccination, symptoms reported have been less severe. Due to extensive data 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 Mpox.

Vaccine Strategies to Prevent Mpox

1. **Post-exposure Prophylaxis (PEP)*** vaccination after known or presumed exposure to Mpox virus can be offered to:
 - a. People who are known contacts to someone with Mpox identified by local health departments via case investigation, contact tracing, or risk exposure assessment
 - i. [Mpox close contact investigation questionnaire](#)
 - ii. [Healthcare exposure risk assessment questionnaire](#)
 - b. People who are aware that a recent sex partner within the past 14 days was diagnosed with Mpox
 - c. GBMSM or transgender or nonbinary people (including adolescents that fall into any of the aforementioned categories) who have had any of the following in the past 14 days
 - i. sex with multiple partners (or group sex)
 - ii. sex at commercial sex venue
 - iii. sex in association with an event, venue, or defined geographic area where Mpox transmission is occurring

**Note that the 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. **Prevention** vaccination prior to exposure to Mpox virus should be offered and encouraged to people who have the highest potential for exposure such as:
 - a. GBMSM, transgender or nonbinary people who in the past six months had
 - i. a new diagnosis of one or more nationally reportable sexually transmitted infections (e.g., chlamydia, gonorrhea, syphilis); OR

- ii. more than one sexual partner
- b. People who have had any of the following in the past six months
 - i. sex at a commercial sex venue; OR
 - ii. sex in association with large public event in geographic area where Mpox transmission is occurring
- c. Sexual partners of people with the above risks
- d. People with HIV infection or other causes of immunosuppression who have had recent or anticipated potential Mpox exposure.

Vaccine Distribution

The JYNNEOS vaccine is available through local health departments. A jurisdiction may request Mpox vaccines by emailing the STD Program at wvstd@wv.gov. Please use "JYNNEOS Request" in the subject line, and include the number of vials requested, the clinic shipping address, and the requesting person's name and contact information.

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 deducted 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 the 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**.
3. Click the **Lot Numbers** blue tab.
4. Click **Search/Add**.
 - i. You are taken to the **Lot Number Maintenance** screen.
5. 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
6. Click **Search**.
 - i. The **Search Results** will appear at the bottom of the screen. There should be no results.
7. To add the vaccine, click the **Add** button.
 - i. You are taken to the **Lot Number Maintenance [Add]** screen.
8. 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** -> Mpox (JYNNEOS) SDV 1-pack
 - vi. Select the **NDC Code** -> 50632-0001-01
9. Click **Add**.

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/Mpox>.
- 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 refreeze 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 vaccines 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 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 the West Virginia Department of Health, Bureau for Public Health, Division of Immunization Services upon request for vaccine accountability.
- Receiving and sending providers must maintain accurate inventory in WVSIS for improved tracking.

Use of JYNNEOS

The standard **FDA-approved** regimen for individuals 18 years of age and older involves a subcutaneous route of administration with an injection volume of 0.5mL, as 2 doses 4 weeks apart (28 days).

Since the U.S. outbreak in summer of 2022, the following has also been authorized under [Emergency Use Authorization \(EUA\)](#):

- The standard subcutaneous injection of 0.5mL, as 2 doses 4 weeks apart (28 days) for people less than 18 years of age.
- 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).
**Preferred in circumstances where JYNNEOS is not readily available as it could increase the number of available vaccine doses by up to five-fold.*

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 Mpox individuals are considered to have lifelong immunity and are not eligible for vaccine.
- Persons exposed to Mpox 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 the vaccine before the 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. 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 days 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 the vaccine before the 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.
 - [JYNNEOS Fact Sheet for Healthcare Providers](#) should be reviewed by providers prior to administering the vaccine.
 - [JYNNEOS Factsheet for Recipients and Caregivers](#) should be provided to patients and caregivers prior to vaccine administration.