# Private Provider Monkeypox Vaccine Guide and Resources

_Last Updated: October 11, 2022_

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Record of Changes Since Last Version

- Watch this section to quickly see updates since the last release of this guide

VDH Planning Assumptions

- On August 9, 2022 the FDA issued an Emergency Use Authorization for JYNNEOS that allows individuals under 18 years to receive the vaccine via the SC injection route, and approves the vaccine for use in individuals over 18 years of age using intradermal (ID) injection route (Subcutaneous can be used for those who are prone to keloids). Dosing is different depending on the route of administration. Intradermal administration will increase the total number of doses available for use by up to five-fold.
- Virginia’s priorities are to administer Post-Exposure Prophylaxis (PEP) in health districts that have confirmed monkeypox cases, as well as Expanded PEP in all health districts.
- For additional information on the CDC’s response to the monkeypox outbreak please visit https://www.cdc.gov/poxvirus/monkeypox/about/cdc-response.html.

Medical Countermeasures Available for Prevention of Monkeypox

Two vaccines for use against smallpox and monkeypox are available for PEP, PrEP or Expanded PEP:

- **JYNNEOS** (also known as Imvamune or Imvanex) is an attenuated, non-replicating live virus, licensed (i.e. approved) by the U.S. Food and Drug Administration (FDA) for the prevention of monkeypox virus infection in individuals 18 years or older. On 8/9/22 the FDA issued an Emergency Use Authorization (EUA) for JYNNEOS. The EUA allows individuals under 18 years to receive the vaccine via the subcutaneous injection route, and approves the vaccine for use in individuals over 18 years of age using either the SC or ID injection routes. Dosing is different depending on the route of administration.

- **ACAM2000** is licensed (i.e. approved) by the FDA for the prevention of smallpox and is made available for use against monkeypox under Expanded Access Investigational New Drug (EA-IND). It contains a live replicating vaccinia virus, licensed for immunization in people who are at high risk for smallpox infection and can also be used in the prevention of monkeypox if exposed or likely exposed to the virus.

VDH does not anticipate near-term use of ACAM2000, and use of the available JYNNEOS vaccine should continue to be focused on PEP and Expanded PEP needs.

Additional Vaccine Resources:

- Smallpox/Monkeypox Vaccine (JYNNEOS) Vaccine Information Statement
- Package Insert - JYNNEOS
- JYNNEOS EUA Fact Sheet for Healthcare Providers
Vaccination Strategies to Prevent Monkeypox

When properly administered before or after a recent exposure, vaccines can be effective tools at protecting people against monkeypox illness.

The following vaccination strategies are being used in the United States and in Virginia:

- **Monkeypox Vaccination for Pre-Exposure Prophylaxis (PrEP):** This approach refers to administering a vaccine to someone at high risk for monkeypox due to occupational exposure. For example, this may apply to laboratory workers who handle live specimens that might contain orthopoxviruses (including monkeypox) or health care workers.

- **Monkeypox Vaccination for Post-Exposure Prophylaxis (PEP):** For the current outbreak, this approach can be considered as “standard PEP” for monkeypox. People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus.

- **Monkeypox Vaccination for Expanded PEP:** For the current outbreak, this expanded approach can be considered as “individual-directed PEP” for monkeypox; public health officials refer to it as “expanded PEP” or “PEP plus-plus” or “PEP++”. People with certain risk factors are more likely to have been recently exposed to monkeypox. This approach aims to reach these groups, even if they have not had a documented exposure to someone with confirmed monkeypox.

**Pre-Exposure Prophylaxis (PrEP)**

The Advisory Committee on Immunization Practices (ACIP) recommends that people whose jobs may expose them to orthopoxviruses, such as monkeypox, get vaccinated with either JYNNEOS or ACAM2000 to protect them if they are exposed to an orthopoxvirus. **Monkeypox vaccine is not routinely recommended for the general public, and is intended to be used in specific groups that have a higher risk of exposure.** The CDC continues to emphasize that using appropriate PPE is enough to prevent transmission in the healthcare setting. See MMWR 71(38); 1216-1219.

**People who should get PrEP, in accordance with ACIP recommendations for Persons at Risk for Occupational Exposure to Orthopoxviruses, include:**

- Clinical laboratory personnel who perform testing to diagnose orthopoxviruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including *Monkeypox virus*.
- Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans, including *Monkeypox virus, replication-competent Vaccinia virus*, or *recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains*.
- Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes.
On September 6, the CDC announced the strategy to expand vaccine eligibility to include PrEP vaccination for healthcare professionals who may be at a higher risk for occupational monkeypox exposure. Virginia’s priority groups remain PEP and Expanded PEP. However, to minimize vaccine wastage, vaccine leftover at the end of a clinic, that would otherwise be wasted, may be administered to individuals with occupational risk within the organization.

Individuals within the organization to consider vaccinating with leftover/extra doses that would otherwise be wasted:

- Nurses (RNs and LPNs) and clinicians who agree to vaccinate with ACAM2000 in the future, if it is needed
- Staff involved with collecting and/or testing of lesion samples
- Staff with prolonged close contact with confirmed or potential monkeypox cases

If you think you should be considered for vaccination but don’t fall into a category above, please consult with the Virginia Department of Health at mpxquestions@vdh.virginia.gov.

PrEP Reminders:

- When possible schedule appointments in groups of 4-5 people to minimize waste.
- Remind staff that using appropriate PPE is the primary action to take in prevention, vaccination is a secondary prevention measure.
- Staff should not be scheduled into a vaccination appointment unless they meet the eligibility criteria for monkeypox vaccination. for PEP or Expanded PEP. Rather, they should be invited only if there is leftover vaccine at the end of the day, as a strategy for minimizing waste.

Majority of healthcare workers and laboratorians should be adequately protected from occupational monkeypox exposure through proper use of CDC recommended infection control practices, which are important to prevent any infection. Infection control protocols for clinic staff collecting a monkeypox specimen (i.e., swabbing monkeypox lesion sites) include, but not limited to: gown, eye protection, gloves and N-95 respirator.

Providers Roles and Responsibilities for PrEP:

- Providers should follow the VDH guidance to ensure compliance with the policy outlined above.
- To limit waste, the provider may consider PrEP for high-risk staff.

Additional Resources:

- [Monkeypox and Smallpox Vaccine Guidance](#)
- [Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Pre-exposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022](#)
Post-Exposure Prophylaxis (PEP)
Following exposure of a confirmed monkeypox case, the CDC recommends that the vaccine be given as soon as possible after exposure, preferably within 4 days.

Consider vaccine for PEP in the following situations:
- During days 0-4 after exposure for intermediate- and high-risk contacts to prevent onset of disease. **The sooner an exposed person gets the vaccine, the better.**
- During days 4-14 after the exposure for high-risk contacts. Vaccination may reduce the symptoms of disease, but may not prevent the disease.
- During days 4-14 after the exposure for intermediate-risk contacts, informed decision making is recommended on an individual basis to determine whether benefits of PEP outweigh the risks.

Provider Roles and Responsibilities for PEP:
- It is important to identify contacts of confirmed or probable monkeypox cases to offer vaccine for PEP within 4 calendar days and to monitor for any early signs of illness.
- Prior to PEP vaccination, individuals should be assessed based on risk factors:
  - If PEP is recommended based on the person’s exposure risk and the person was previously vaccinated for smallpox more than three years ago, then the person should be revaccinated.
  - PEP is not recommended for contacts with Low/Uncertain or No Risk groups.
- When coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox.
- When considering PEP for children 6 months old, consultation with VDH is required.

Expanded Post-Exposure Prophylaxis (Expanded PEP)
The CDC is working to increase vaccine supply to the states and to increase access and eligibility for vaccination.

Groups Recommended for Monkeypox Expanded PEP in Virginia:

**Eligible recipients include any person who identifies as being one or more of the following:**
- People, of any sexual orientation or gender, who have had anonymous or multiple (more
than one) sexual partners in the last two weeks; or
- Sex workers of any sexual orientation or gender; or
- Staff of any sexual orientation or gender, at establishments or events where sexual activity occurs; or
- Any person of any sexual orientation or gender who is living with HIV/AIDS; or
- Any person of any sexual orientation or gender diagnosed with any sexually transmitted infection in the past three months.

When coupled with self-isolation and other prevention measures when symptoms first occur, Expanded PEP may help slow the spread of the disease in areas with large numbers of monkeypox cases.

**Note:** Persons living with HIV or other immune-compromising conditions may be at higher risk for severe outcomes and should be a high priority for vaccination, specifically JYNNEOS. For more information about persons living with HIV, please refer to CDC Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV.

**Provider Roles and Responsibilities for Expanded PEP:**
- Ensures public messaging (e.g., website content) is up-to-date with resources on how to access vaccines in their practice
  - Ensures all staff answering phones know the process and can provide correct information
  - Does not refer callers seeking a vaccine to the statewide call center. If necessary, providers may seek assistance from their LHD on behalf of their patients.
- Ensures adequate staff are trained on ID administration
- Providers should be able to recommend or not recommend vaccination based on individual risk factors and any clinically significant contraindications.

**JYNNEOS Requests and Prescribing Information**

**JYNNEOS Requests**
Providers will need to complete a VERIP preregistration. This preregistration will allow the provider to submit their facility and contact information as well as complete the VDH attestation. After doing so, private providers will be enrolled in VaxMaX if they do not already have an account. Once enrollment is complete, the provider can request JYNNEOS in VaxMaX as stated above.

**HHS Provider Agreement**

The Virginia Department of Health (VDH) is planning on allowing private providers to order the JYNNOES vaccine through a portal called VaxMaX.

VDH will utilize VERIP (Virginia Electronic Registration for Immunization Programs) for sharing of the HHS Provider Agreement allowing monkeypox vaccinating providers to view the HHS
agreement and acknowledge that they have reviewed and will abide by it. Per the CDC requirements, every vaccine provider must receive the HHS Provider Agreement with every order placed and/or every shipment of monkeypox vaccines.

Per the HHS & CDC - “With use of the JYNNEOS or ACAM2000 vaccine provided at no cost by the US government (this vaccine), the provider and provider’s 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 2 below.”

This vaccine remains property of the United States government and subject to the terms of this Agreement until the dose is administered to the vaccine recipient.” Please see the HHS Provider Agreement webpage for additional information.

Below is the request/delivery schedule for JYNNEOS:

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Redistribution of Vaccine
Redistribution of the monkeypox vaccine is not authorized for private providers. Providers, practices, or other affiliated locations that wish to administer the monkeypox vaccine should email vaxmax_help@vdh.virginia.gov to become an enrolled monkeypox vaccine provider.

JYNNEOS for Clients Under 18 Years Old
On August 9, 2022, the FDA released an EUA for JYNNEOS that allows individuals under 18 years to receive JYNNEOS vaccine SC. Parental consent is required for minors. For individuals under 18 years, there is no longer an investigational new drug (IND) process required when administering PEP.

Additional information to note:
- Intradermal administration is not authorized for individuals less than 18 years of age.
- The pediatric dose is the same as the SC dose for adults (two doses of 0.5 mL SC 4 weeks apart).
- For more information, see the EUA Fact Sheet for Healthcare Providers

JYNNEOS Storage and Handling
Refrigerated Vaccine
- VDH ships vaccine under refrigerated conditions (2°C to 8°C). VDH will calculate and provide the 8-week beyond use date for JYNNEOS at the time of transportation.
Once thawed, vaccine vials that are not currently being used should be placed in the refrigerator between 2°C and 8°C (36°F and 46°F). Do NOT refreeze the thawed vaccine. Use the beyond-use date labels for this vaccine to track storage dates/times.

Beyond-use date/timing:
- 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.

NOTE: This information has been provided by the vaccine manufacturer based on available supportive stability data. Please be aware that this differs from the JYNNEOS package insert.

For more information, see the JYNNEOS EUA and CDC Vaccine Preparation and Administration Summary.

Frozen Vaccine

- Vaccines arriving frozen can be stored under manufacturer guidelines under either frozen conditions at -25 to -15°C (-13 to +5°F) until the expiration date or refrigerated at 2-8°C (36-46 °F) for up to 8 weeks. CDC ships vaccine under frozen conditions.

Should there be questions about viability of vaccine or vaccine waste, sites should quarantine vaccine in the refrigerator and direct questions to VDH staff at mpxquestions@vdh.virginia.gov or call (804) 786-4326. Any JYNNEOS vaccine that is deemed non-viable by VDH should be considered wasted. Wasted doses must be recorded in VaxMax.

Vaccines should be stored in the original package to protect from light if possible. Please note the vaccine expiration date is not printed on the individual vial. Any vaccine distributed by VDH outside of the original manufacturer carton will be wrapped in paper to protect from light and placed in a plastic container which is labeled with the original lot and expiration date from the carton. The receiving site should store in packaging to ensure storage in accordance with manufacturer instructions.

Ancillary Supplies

The CDC suggests using needles for ID injection that are 26-27 gauge and ¼ -½" with short bevels along with a low dead-space syringe, such as a tuberculin syringe (or similar 1cc syringe). Ancillary supplies are not included in vaccine shipments.

Provider Roles and Responsibilities for Vaccine Administration

Intradermal Administration Training for JYNNEOS

Per the HHS Amendment to the PREP Act on October 3, 2022, “all authorized providers (of monkeypox vaccine) must administer all countermeasures in accordance with all relevant requirements and recommendations of Centers for Disease Control and Prevention (CDC), and
consistent with the scope of the U.S. Food and Drug Administration’s (FDA’s) approval, authorization, and any applicable expanded access requirements of FDA’s protocol.”

Training on the ID injection route is strongly encouraged prior to administering JYNNEOS as an ID injection. The ID technique requires a skill-based training component because it is not a commonly used method and may be challenging to achieve the correct placement.

- Intradermal Training
  - Intradermal Vaccination Administration Training Checklist is recommended to use during trainings or as an aid in the clinic setting.
- Intradermal training resources:
  - Monkeypox – Administering JYNNEOS Smallpox Vaccine
  - VDH Monkeypox Training Resources
  - Intradermal Injection Training Pads are valuable training aids and can be purchased online for a modest cost.

JYNNEOS Administration Guidance

If your staff are experiencing challenges removing the cap of the JYNNEOS vials, please see these instructions from the manufacturer.

Intradermal Administration of JYNNEOS Guidance

Intradermal administration remains the preferred route of administration for JYNNEOS vaccine. CDC has provided exceptions to ID administration, which include:

- Those who have a contraindication to ID injection (e.g., those with a history of keloid formation or those unable to tolerate ID injections)
- Those under 18 years of age

In addition, CDC provides this additional guidance related to failed intradermal vaccine administrations:

- ID administration, no wheal, and no leakage = valid dose
- ID administration, no wheal and visible leakage = repeat ID dose at least 2 inches away from original dose
- Two ID administrations with visible leakage = 3rd dose administered subq 0.5mL

Please refer to the CDC’s Interim recommendations for JYNNEOS vaccine administration errors and deviations for additional information..

The HHS Monkeypox Vaccine Program Provider Agreement makes clear that while a subcutaneous route of administration utilizing 0.5 mL per injection is still permitted (per original FDA approval), it should only be utilized for those who have a contraindication to ID injection (e.g., those with a
history of keloid formation or those unable to tolerate ID injections). Therefore, **vaccinators should aim to become proficient in ID administration.**

Provide the second dose of the series in 28 days, following a successful administration; screen for contraindications and precautions. Use clinical judgment to decide what route of administration should be for the second dose. [CDC Interim Guidance](https://www.cdc.gov) provides information regarding interchangeability of dosing regimens. 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.

Additionally, vaccinators should screen for contraindications and precautions at each clinical visit. The ID route is preferred, unless the patient has a contraindication or precaution or an attempt at ID administration has failed during the same clinical encounter.

**Training Resources:**
- [JYNNEOS Intradermal Vaccine Checklist](https://www.cdc.gov)
- [CDC JYNNEOS Smallpox and Monkeypox Vaccine Intradermal Vaccine Preparation and Administration Summary: Alternative Dosing Regimen](https://www.cdc.gov)

**Subcutaneous Administration of JYNNEOS Guidance**
*There is no special training needed to administer dosing using the SC injection route as it is a common injection technique.* See the VDH website, “[Monkeypox - Administering JYNNEOS Smallpox Vaccine](https://www.cdc.gov)” for additional information.

**Limiting JYNNEOS Vaccine Wastage**
Providers should schedule enough vaccine appointments to utilize a full vial of vaccine.
- In the event there is vaccine leftover at the end of a monkeypox vaccine clinic, that would otherwise be wasted, providers should:
  - First try to contact individuals on their established interest/waiting list to see if they are available to come in for vaccination before the vaccine reaches its beyond use date (BUD).
  - If providers are not successful in pulling from the interest/waiting list, they may provide leftover doses of vaccine, that would otherwise be wasted, to staff. For more guidance, see [Pre-Exposure Prophylaxis (PrEP)](https://www.cdc.gov) above.

**Additional Resources:**
- [Monkeypox Screening and Consent Form](https://www.cdc.gov)
- [JYNNEOS Standing Order template](https://www.cdc.gov)
Documentation of Doses Administered
Obtain informed consent using the standardized Monkeypox Screening and Consent Form for the Public. All monkeypox vaccine administered must be entered in VIIS within 24 hours.

Vaccine Adverse Reaction Reporting
Vaccine adverse events for monkeypox vaccines will be monitored through Vaccine Adverse Events Reporting System (VAERS) along with CDC vaccine surveillance systems: the Vaccine Safety Datalink (VSD) and the Clinical Immunization Safety Assessment (CISA) team (Vaccine Safety Monitoring | Vaccine Safety | CDC).

The CDC and FDA strongly encourage and request safety reporting by healthcare professionals to VAERS for all U.S. licensed vaccines, including JYNNEOS. Report adverse events following vaccination that, in your professional judgment, are medically important or clinically significant, even if you are not sure if the vaccine caused the event.

To report in VAERS, go to Report an Adverse Event on the VAERS website. Choose Report Online (the preferred method). For more information, visit the VAERS FAQs, email questions to info@VAERS.org, or call 1-800-822-7967 from Monday through Friday between 9 a.m. to 5 p.m. Eastern time.

Vaccine Billing
- CDC/SNS is providing the vaccine and the antiviral medication at no cost to the state or to the client.
- A vaccine administration fee can be billed by private providers who can bill patients or insurance for the vaccine administration/clinic appointment but they should not balance bill patients.

Vaccine Waste Management
Should there be questions about viability of vaccine or vaccine waste, sites should quarantine vaccine in the refrigerator and direct questions to VDH staff at mpxquestions@vdh.virginia.gov. If VDH confirms the vaccine is viable, the provider can proceed with normal operations. If VDH confirms the vaccine is NOT viable, the provider should complete the Monkeypox Wastage Survey located in VaxMax. Providers will need to submit their provider specific information as well as vaccine information including lot number, expiration date, and reason for wastage.

Other key aspects of vaccine wastage to keep in mind:
  1. If providers are unable to draw 5 doses in each vial, "insufficient volume" should be reported as the reason for waste in VaxMax. For example, if a site is only able to draw 3 doses, the site reports insufficient volume and enters the waste amount as 2 (i.e., 2 out of the 5 doses were not used).
  2. Failed intradermal attempts are to be recorded as wastage.
3. Some vials may not contain sufficient volume to obtain 5 full doses. This is reported in VaxMaX as a wasted dose with “Insufficient Volume” as the reason for the waste.

For questions regarding the VaxMaX wastage reporting process, please contact VaxMaX_help@vdh.virginia.gov.