Private Provider Monkeypox Vaccine Guide and Resources

Updated November 22, 2022

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Record of Changes Since Last Version

- Simplified vaccine eligibility criteria & removed prioritization recommendations (PEP, PEP++, PrEP)

Virginia Department of Health (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 subcutaneous (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 or who refuse ID injections). 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 align with the national vaccine strategy that outlines three exposure categories: Post-Exposure Prophylaxis (PEP), Expanded PEP (PEP++) and Pre-Exposure Prophylaxis (PrEP). For additional information on these exposure categories please see the HHS Operational Planning Guide, Vaccination Strategies.
- For additional information, visit the CDC's response to the monkeypox outbreak page.

Medical Countermeasures Available for Prevention of Monkeypox

Two vaccines for use against monkeypox are available through the SNS. **Either JYNNEOS or ACAM2000 can be used** following risk-benefit discussions and a review of any conditions that could increase risk for serious adverse events.

- **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 August 9, 2022, the FDA issued an 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. If an individual refuses to receive the vaccine via ID route, the injection may be given via SC route if preferred, especially if they would not otherwise receive the vaccine. The dosing is different depending on the route of administration.
    - Smallpox/Monkeypox Vaccine (JYNNEOS) Vaccine Information Statement
    - Package Insert - JYNNEOS
    - JYNNEOS EUA Fact Sheet for Healthcare Providers
- **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.

- Medication Guide for vaccination with ACAM2000
- ACAM2000 Package Insert
- Administering ACAM2000 Smallpox Vaccine Videos

VDH does not anticipate near-term use of ACAM2000, and use of the available JYNNEOS vaccine should continue to be focused on certain high risk individuals. For more information, visit the VDH Monkeypox Vaccine Guidance Provider website.

Monkeypox Vaccination Criteria

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

Eligibility Criteria

The following individuals are eligible to receive monkeypox vaccination[1,2]:

- Those who, within the past 14 days, have had an intermediate to high risk exposure to a known and documented monkeypox case
- Those with certain risk factors and recent experiences that might make them more likely to have been recently exposed to monkeypox:
  - Person (of any sexual orientation or gender) who has had anonymous or multiple (more than 1) sexual partners in the last 2 weeks
  - Person (of any sexual orientation or gender) diagnosed with any sexually transmitted infection in the past three months
  - Person (of any sexual orientation or gender) who is living with HIV/AIDS
  - Staff (of any sexual orientation or gender) at establishments or events where sexual
  - Sex workers (of any sexual orientation or gender)
- Those whose jobs may expose them to orthopoxviruses, such as monkeypox; examples include:
  - Healthcare providers who are administering ACAM2000
  - Laboratorians handling monkeypox specimens

[1]Individuals may attest to meeting one or more of the eligibility criteria for vaccination, however should not be required to attest to a specific criterion nor should they be asked details about their eligibility.
[2]At this time, most clinicians and laboratorians in the United States are not advised to receive the monkeypox vaccine for pre-exposure prophylaxis. For additional information regarding PrEP, visit CDC Monkeypox and Smallpox Vaccine Guidance and ASPR/HHS Vaccination Strategies.

Optimal Time for Vaccination:

Getting vaccinated before exposure to monkeypox provides the best chance to prevent disease. For best protection, 2 doses of JYNNEOS vaccine spaced 28 days apart are recommended. Following exposure of a confirmed monkeypox case, the CDC recommends that the vaccine be given as soon as possible, preferably within 4 days.

Consider vaccine for 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 receives 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 pre-exposure prophylaxis outweighs the risks.

Note: JYNNEOS can be administered to people with immunocompromising conditions. JYNNEOS vaccine doses should be prioritized for people who are at high risk for severe disease from monkeypox (including, but not limited to, people living with HIV infection, pregnancy, or other immunocompromising conditions).

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.

VDH is relying on partners to reach affected communities and as such, is stressing that messaging should be fact-based to avoid stigmatizing these populations. Partners can find more information on the VDH Monkeypox Communication Resources web page or on the CDC's "Reducing Stigma in Monkeypox Communication and Community Engagement" web page.

CDC also maintains a webpage (Preferred Terms for Select Population Groups & Communities) that provides some preferred terms for select population groups; these terms attempt to represent an ongoing shift toward non-stigmatizing language. CDC recommends using this section as a guide and inspiration to reflect upon word choice and choose words carefully, inclusively, and appropriately for a specific use and audience. Best practices include engaging people from the population or community of focus to find out what they prefer.

On September 6, 2022, 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. If a healthcare setting has leftover/extra doses that would otherwise be wasted, consider vaccinating:

- Nurses 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
- Staff who conduct in-home visits or have other contact with high risk individuals

Vaccination Reminders:

- Practices should continue to schedule appointments in groups of 4-5 in order to minimize waste. Remind staff that using appropriate PPE is the primary action to take in prevention, while vaccination is a secondary prevention measure. Most healthcare workers 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. HCP are reminded that deroofing or lancing lesions is not recommended as the use of sharps near the lesions increases the likelihood of occupational exposure.

Additional Resources:

- CDC 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
- Health Care Personnel Exposures to Subsequently Laboratory-Confirmed Monkeypox Patients — Colorado, 2022. MMWR September 23, 2022 / 71(38);1216–1219

JYNNEOS Requests and Prescribing Information

Private Provider Enrollment Process

1. Review the HHS Provider Agreement to understand requirements of monkeypox vaccine providers and prepare to attest to these requirements.

2. Email the VaxMaX Help Desk at vaxmax_help@vdh.virginia.gov to declare intent to order and administer the monkeypox vaccines in accordance with the HHS Provider Agreement requirements. VaXMaX will provide next steps for attestation.

3. Review the following VDH resources that may be adapted to fit the private provider practice:

- Vaccination Checklist
- Monkeypox Vaccine Screening and Consent Form Template
- Statewide Monkeypox Vaccine Standing Order
- Intradermal Injection Training Resources

Please note the JYNNEOS vaccine is intended to be administered intradermally. Staff **must be adequately trained** on proper ID administration technique. It is recommended that hands-on training be conducted to ensure adequate technique.

HHS Provider Agreement

VDH will utilize VERIP 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 each 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.

JYNNEOS Vaccine Requests

Requests are made via VaxMax. If you are not already a monkeypox vaccinator, see above **Private Provider Enrollment Process** section for more information.

Below is the request/delivery schedule for JYNNEOS:

For Orders Submitted by Tuesday 2:00 PM Tuesday 2:00 PM: Provider order submission cutoff Thursday/Friday: Doses delivered to provider	**For Orders Submitted by Thursday 2:00 PM** Thursday 2:00 PM: Provider order submission cutoff Tuesday/Wednesday: Doses delivered to provider

Redistribution of Vaccine

As of October 11, 2022, **VDH no longer allows monkeypox vaccine redistributions to other facilities/providers**, unless deemed necessary after consultation with VDH (email: vaxmax_help@vdh.virginia.gov for consultation). Private providers should enroll as monkeypox providers using the steps outlined in the **Private Provider Enrollment Process**, rather than requesting vaccines from the LHD.

The following are exceptions in which redistribution *may be allowed* after consultation with VDH:

- A private provider has vaccines that are close to expiring and sending it to a local health district (LHD) or another provider for immediate use will prevent waste.
- A local health district or private provider is in immediate need of vaccines to adequately cover a clinic or event.

*Redistributions **must** be recorded in VaxMaX. Unauthorized redistribution of vaccines and failure to report redistributions in VaxMaX will result in future vaccine orders being withheld or delayed.*

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; administration must be via the SC route.

- 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 Shipping Conditions

- **If arriving from VDH**
    - All JYNNEOS vaccines **prepared by VDH** will be distributed to sites with instructions to **store under refrigerated conditions (2°C to 8°C)** upon arrival. VDH staff will calculate and provide the 8-week beyond use date (BUD) for JYNNEOS at the time of transportation. Doses will arrive refrigerated (not frozen) and should be placed in the refrigerator immediately; the **BUD will be 8 weeks from the ship date**.
    - **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 original carton.**

- **If arriving directly from the federal government**
    - If vaccine is shipped directly from the federal government, then the vaccine may arrive **frozen**. Vaccines arriving frozen can be stored under manufacturer guidelines under either frozen conditions at -25 to -15ºC until the expiration date printed on the carton or refrigerated at 2-8°C for up to 8 weeks.

Storage and Handling

Use BUD labels for this vaccine to track storage dates/times.

- Beyond-use date/timing:
    - Frozen: Between -25°C and -15°C (-13°F and +5°F).
        - If the vaccine was received frozen and has maintained frozen temperatures, the vaccine may be used until the expiration date printed 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
    - Thawed and at Refrigerated Temperatures: Between 2°C and 8°C (36°F and 46°F).
        - Once thawed, vaccine vials that are not currently being used should be placed in the refrigerator; do NOT refreeze the thawed vaccine.
        - *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.

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 and discarded in a Pharmaceutical Hazardous Waste box.

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 Monkeypox Vaccination

- It is important that providers identify contacts of confirmed or probable monkeypox cases to offer vaccine within 4 calendar days, and to monitor for any early signs of illness.
- Prior to vaccination, individuals should be assessed based on risk factors:
    - If a monkeypox vaccine is recommended based on the person's exposure risk and the person was previously vaccinated for smallpox more than three years ago, the person should be revaccinated.
    - Monkeypox vaccine is not recommended for contacts with Low/Uncertain or No Risk Groups.
- Providers should be able to recommend or not recommend vaccination based on individual risk factors and any clinically significant contraindications.
- **Providers should ensure they have the most up to date eligibility criteria and resources, as well as utilize appropriate language to address high risk individuals.**
    - Ensure usage of non-stigmatizing language.
    - Ensure forms do not contain requirements for individuals to provide eligibility specific information or select which criteria they meet (i.e., individuals should have the ability to answer "Yes" or "No" in response to a general eligibility question).
    - Ensure all staff answering phones know the process and can provide correct information.
- Ensures public messaging (e.g., website content) is up-to-date with resources on how to access vaccines in their practice
    - Does not refer callers seeking a vaccine to the statewide call center. If necessary, providers may seek assistance from their local health department on behalf of their patients
- Ensures adequate staff are trained on ID administration (see below under Intradermal Administration Training for JYNNEOS)
- Ensures all vaccinating providers are following the VDH guidance, as well as the HHS Provider Agreement, to ensure compliance.

- To limit waste, the provider should attempt to schedule enough appointments according to the number of doses per vial, and may consider PrEP for high-risk healthcare staff if doses remain that would otherwise be wasted.

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 required 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 may be used 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 for guidance and additional information.

Intradermal Administration of JYNNEOS Guidance

Intradermal administration remains the preferred route of administration for JYNNEOS vaccine. CDC 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
- Attempt(s) at ID administration failed during the same clinical encounter
- Those who refuse to receive the vaccine intradermally and if not administered SC, would otherwise not receive the vaccine; we want to ensure all high risk individuals receive the vaccine if they want it

In addition, CDC provides additional guidance related to failed intradermal vaccine; 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.**

Interchangeability of Dosing Regimens and Timing of Vaccination

- When necessary in eligible individuals, the dosing regimens are interchangeable. CDC Interim Guidance provides more information and examples of when interchangeability of dosing regimens is appropriate.
- Provide the second dose of the series, if necessary, in 28 days, following a successful administration.
- As a best practice, vaccinators should screen for contraindications and precautions at each clinical visit.
- Vaccination is not expected to provide benefit if it is given after onset of signs or symptoms of monkeypox, after a diagnosis of monkeypox, or after recovery from monkeypox disease. Monkeypox infection likely confers immune protection.

Resources:

- JYNNEOS Intradermal Vaccine Checklist
- CDC JYNNEOS Smallpox and Monkeypox Vaccine Intradermal Vaccine Preparation and Administration Summary: Alternative Dosing Regimen

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"* for additional information.

Additional Resources:

- Monkeypox Vaccine Screening and Consent Form Template
- Statewide Monkeypox Vaccine Standing Order
- JYNNEOS Standing Order template

Documentation of Doses Administered

Screen individuals for vaccine eligibility, including contraindications and precautions. If a provider does not already have one for their practice, they may use this template (Monkeypox Vaccine Screening and Consent Form). All monkeypox vaccines administered must be entered into the **Virginia Immunization Information System (VIIS)**.

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 vaccination provider must report all serious adverse events following administration of JYNNEOS or ACAM2000 vaccine and vaccine administration errors to VAERS. For more information about reporting, visit CDC Reporting of Adverse Events.

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 monkeypox vaccines at no cost to the state, provider, or client.
- A vaccine administration fee can be billed by private providers to a third party insurance. A provider may also bill insurance for the clinic visit/appointment. However, the provider should not bill the patient directly for the vaccine itself or the vaccine administration, regardless of insurance status.

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 document the waste in VaxMax.

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.