Private Provider Mpox Vaccine Guide and Resources

Updated March 8, 2023

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What is New and Noteworthy Since Last Version

- **Continued emphasis on vaccination:** Mpox vaccination should continue to be offered to people with the highest potential for exposure to mpox.
- **Updated guidance**: People with HIV infection or other causes of immunosuppression who have had recent or anticipate potential mpox exposure should be vaccinated against mpox.
- **New emphasis on inclusion of adolescents:** The principal risk group was reworded as "Gay, bisexual, and other men who have sex with men, and transgender or nonbinary people (including adolescents who fall into any of the aforementioned categories) … "
- **Language revision:** "Expanded post-exposure prophylaxis (PEP++)" was removed as a category. Vaccination of people previously recommended for PEP++ will be included in PEP recommendations.
- **Language revision:** "Pre-exposure prophylaxis (PrEP)" was replaced with "vaccination prior to exposure" to align with language for risk-based recommendations used for other vaccine-preventable diseases.

Virginia Department of Health (VDH) Planning Assumptions

- The U.S. Department of Health and Human Services (HHS) announced an enhanced nationwide vaccination strategy to mitigate the spread of mpox.
- JYNNEOS will be the primary vaccine offered in Virginia for mpox. If JYNNEOS is unavailable, ACAM2000 *may* be a suitable alternative, but its use must first be approved by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) as it must follow the expanded access Investigational New Drug (EA-IND) protocol.
- On August 9, 2022 the FDA issued an Emergency Use Authorization (EUA) 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 either the SC or intradermal (ID) injection routes. 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 Post-Exposure Prophylaxis (PEP) and vaccination prior to exposure to mpox for any persons deemed eligible per the eligibility criteria set forth by the CDC.
- The US Government will deploy Strategic National Stockpile (SNS) vaccine supply to jurisdictions in phases, then VDH will allocate them to Local Health Districts (LHDs). ***Note: once deployed, products cannot be returned to the SNS.***

Mpox Public Health Emergency Expiration

On December 2nd, 2022, HHS announced that the Public Health Emergency (PHE) mpox will not be renewed; the PHE expired January 31st, 2023. HHS will continue to closely monitor mpox cases and encourage all at-risk individuals to get vaccinated. With this PHE expiration, the Virginia statewide standing order was also revoked. To continue administering the mpox vaccine, LHDs should use the CDC standing order templates (subcutaneous and intradermal) for administering the JYNNEOS vaccine.

Monkeypox Name Change

On November 11, 2022, the World Health Organization (WHO) announced the adoption of "mpox" in place of the "monkeypox" naming convention. Both names will be used simultaneously for one year while "monkeypox" is phased out. Mpox will become a preferred term, replacing monkeypox, after a transition period of one year. For more information visit CDC Changes Monkeypox Terminology to Mpox.

Vaccination for Mpox Prevention

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

Two vaccines may be used to prevent mpox:

- **JYNNEOS** (also known as Imvamune or Imvanex) is used for the prevention of smallpox and mpox among people at high risk for infection. During the current mpox outbreak, **JYNNEOS is the only vaccine being used in the U.S.**
- **ACAM2000** is used to prevent smallpox among people at high risk for infection. It has not been used in the current outbreak.

Vaccine Eligibility Criteria

As of February 17, 2023, VDH simplified its mpox eligibility criteria to reflect the CDC criteria. Please refer to Mpox Vaccination Basics CDC website to review eligibility for the mpox vaccine.

JYNNEOS Administration and Ordering Guidance

There are several expectations to support the planning and administration of the mpox vaccine including:

- **Virginia removed residency requirements** and now allows for non-residents of Virginia to receive the JYNNEOS mpox vaccine.
- Providers are expected to abide by the beyond use dates for the vaccines and discard any vaccine deemed not viable.
- If your staff are experiencing challenges **removing the cap of the JYNNEOS vials**, please review

the manufacturer instructions for assistance.

- As of December 2nd, **VDH elected to adopt relaxed guidance for SC versus ID vaccine administration routes.** During this outbreak, the alternative regimen (ID route) is preferred, but the JYNNEOS vaccine may be administered subcutaneously using the standard regimen (SC route).
- CDC recommends that health care providers always have both SC and ID vaccine administration options available. This aims to reduce potential stigma and allows patients to receive the vaccine based on their preference.
- **All vaccine providers in Virginia must report any doses administered to the Virginia Immunization Information System (VIIS).**

Intradermal Administration for JYNNEOS

Per the HHS Amendment to the PREP Act on October 3, 2022, *"all authorized providers (of mpox 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. It is the providers' responsibility to provide personnel with training, developed by the provider or other acquired training material, ensure staff who administer the vaccine (new, temporary, and those who lack prior training/experience) are properly trained with vaccine administration via ID route. Intradermal injection training material available on VDH webpage is a supplemental resource and should not be the sole source of training material, as hands-on training is a requirement as well.

Intradermal Administration of JYNNEOS Guidance

Intradermal administration remains the preferred route of administration for JYNNEOS vaccine. Thus, **vaccinators should aim to become proficient in ID administration.**

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 ID for any reason, may receive it SC

Please reference the HHS Monkeypox Vaccine Program Provider Agreement for expectations around SC versus ID injections. Additionally, refer to the CDC's Interim recommendations for JYNNEOS vaccine administration errors and deviations for additional guidance related to failed ID vaccine administrations.

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.
- 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 mpox, after a diagnosis of mpox, or after recovery from mpox disease. Mpox infection likely confers immune protection.
- Provide the second dose of the series, when indicated, in **28 days**, following a successful administration.
    - As recommended by the CDC, clients who contract mpox prior to receiving their second dose of the vaccine should not receive the second dose.

Optimal Time for Vaccination

Getting vaccinated before exposure to mpox 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 mpox 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 outweigh 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 mpox (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.

Coadministration

For information regarding coadministration with other vaccines, visit CDC JYNNEOS Interim Considerations - Coadministration of JYNNEOS Vaccine with Other Vaccines.

JYNNEOS for Patients 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.

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 SC dose is the same as the adult SC dose (2 doses; 0.5 mL 4 weeks apart).
- For more information, see the EUA Fact Sheet for Healthcare Providers

Private Provider Enrollment Process

1. Review the HHS Mpox Vaccination Program Provider Agreement to understand requirements of mpox 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 mpox vaccines in accordance with the HHS Provider Agreement requirements. VaXMaX will provide next steps for attestation.
3. See the Resources section below for VDH and CDC resources to use in your practice.

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 mpox 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 mpox 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.” Please see the HHS Provider Agreement webpage for additional information.

Safety

For information regarding safety (i.e., contraindications and precautions), visit CDC JYNNEOS Interim Considerations - Safety.

Vaccine Adverse Reaction Reporting

- Vaccine adverse events for mpox 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. ET.

V-Safe

- Individuals getting vaccinated should be encouraged to enroll in V-safe.
- V- safe is used for safety tracking of mpox vaccine. CDC's V-safe after vaccination health checker is a smartphone-based system that uses text messaging and web surveys to provide personalized and confidential health check-ins.
- Participants can tell CDC how they, or their child or dependent, feel after they receive any dose of a COVID-19 vaccine (including an updated bivalent booster) or an mpox vaccine.
- Participation in V-safe helps CDC monitor the safety of vaccines.

Screening for Vaccine Eligibility and Contraindications

Screen individuals for vaccine eligibility, including contraindications and precautions. If a provider or practice does not already have a screening and consent form for mpox vaccination, they may use this template: VDH Private Provider Mpox Vaccine Screening & Consent Form Template.

JYNNEOS Vaccine Requests

Requests are made via VaxMax. If you are not already a mpox 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:

VDH does not allow mpox vaccine redistribution to other facilities/providers, unless deemed necessary after consultation Pharmacy Services and the VDH Vaccine Allocation team (email: vaxmax_help@vdh.virginia.gov for consultation).

Private providers should enroll as mpox providers using the steps outlined above in the Private Provider Enrollment Process, rather than requesting vaccines from their local health district (LHD).

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

- Vaccine is close to expiring and sending it to a LHD or another provider for immediate use will prevent waste.

- Another private provider or LHD is in immediate need of vaccine to adequately cover a clinic or event.

If a redistribution is approved, it **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 Shipping Conditions

If vaccine is arriving from VDH:

- **Effective July 19, 2022**, 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. DPS staff will calculate and provide the 8-week beyond use date for JYNNEOS at the time of transportation. Doses will arrive refrigerated (not frozen) and should be placed in the refrigerator immediately; the **beyond use date will be 8 weeks from the ship date**.
- **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 labeled with the original lot and expiration date from the carton**.

If vaccine is arriving directly from the federal government:

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

Please note the vaccine expiration date is not printed on the individual vial. Expiration date by lot number can be found on ASPR's SNS Products webpage. If possible, vaccines should be stored in the original package to protect from light.

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.
    - 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 Mpox Vaccination

Vaccinating High Risk Individuals

- It is important that providers identify contacts of confirmed or probable mpox 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 mpox 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. Mpox 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.

Avoid Stigmatizing Language/Actions

- 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.
- Providers should address patients' concerns about vaccination
    - Ensure that patients with concerns about ID administration due to potential stigma or other personal reasons are offered SC doses.

- During this outbreak, the alternative regimen (ID route) is preferred and recommended by CDC, but the JYNNEOS vaccine may be administered using the standard regimen (SC route).
- CDC recommends that healthcare providers have both SC and ID vaccine administration options available on site so that those unable or unwilling to receive the ID regimen, can receive the SC regimen.

Stay Up to date with Recommendations

- Ensure public messaging (e.g., website content) within your practice is up to date with resources on how to access vaccines in their practice
  - Please do 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 or refer the patient to their respective local health department.

Compliance

- Ensure adequate staff are trained on ID administration.
- Ensure 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.

Vaccine Billing

- CDC/SNS is providing mpox 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 via VaxMaX. For questions regarding the VaxMaX wastage reporting process, please contact VaxMaX_help@vdh.virginia.gov.

Other key aspects of vaccine wastage to keep in mind:

- 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).
- Failed intradermal attempts are to be recorded as wastage.

- 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.

Resources

General

- VDH Mpox Vaccine Guidance Provider website
- CDC Mpox and Smallpox Vaccine Guidance
- Health Care Personnel Exposures to Subsequently Laboratory-Confirmed Mpox Patients — Colorado, 2022. MMWR September 23, 2022 / 71(38);1216–1219

JYNNEOS

- Emergency Use Authorization (EUA) for JYNNEOS
- Smallpox/Mpox Vaccine (JYNNEOS) Vaccine Information Statement
- Package Insert - JYNNEOS
- JYNNEOS EUA Fact Sheet for Healthcare Providers
- Use of JYNNEOS (Smallpox and Mpox Vaccine, Live, Nonreplicating) for Pre-exposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices
- CDC’s JYNNEOS Smallpox and Monkeypox Vaccine Preparation and Administration Summary (Intradermal Administration)
- VDH Private Provider Mpox Vaccine Screening & Consent Form Template (may be modified to fit the needs of your practice)

Training

- How To Do an Intradermal Injection
- VDH Administering Intradermal Injections

Health Equity and Stigma

- CDC Partnering for Vaccine Equity Guide & Resources
- CDC Reducing Stigma in Mpox Communication and Community Engagement
- CDC Preferred Terms for Select Population Groups & Communities
- HRC Glossary of Terms - Human Rights Campaign
- WHO Risk communication and community engagement public health advice on understanding, preventing and addressing stigma and discrimination related to monkeypox