

# MONKEYPOX VACCINE PROVIDER INFORMATION SHEET

## Concept of Operations for Vaccine Administration

The current Monkeypox response framework includes a diverse network of “Points of Vaccination” (POV) that include public health sites (State Health Centers and CMHD clinics), STD treatment centers, FQHC/FQHC lookalikes, and other sites who have a relationship with the primary impacted population. These sites may take walk-in clients who express a need for vaccine or will be referred to the POVs by public health agencies.

## Vaccine Prioritization

As of the date of this document, the current prioritization of the JYNNEOS vaccine is recommended to prioritize first those needing Post Exposure Prophylaxis (PEP), then those needing enhanced PEP. Due to the limited quantity of vaccine available, pre-exposure prophylaxis (PrEP) is recommended in limited situations specifically for individuals meeting the criteria below.

- **Priority 1 - PEP:** [High or Intermediate-risk](#) case contacts identified by public health via case investigation, contact tracing, and risk exposure assessments (this may include sexual partners, household contacts, and healthcare workers) *[Note: This would include contacts named by the case during an investigation or individuals coming forward and reporting to public health high or intermediate risk contact with a known monkeypox case]*
- **Priority 2 – Enhanced PEP:**
  - Individuals who report having a sex partner or other direct contact (e.g., unprotected contact between a person’s skin or mucous membranes and the skin, lesions, or bodily fluids) in the past 14 days with an individual showing symptoms consistent with monkeypox, such as a rash or sores; **OR**
  - Gay, bisexual, or other men who have sex with men, and/or transgender, gender non-conforming, or gender non-binary persons who have had multiple (2+) or anonymous sex partners in the past 14 days **AND meet one of the following criteria:**
    - Have knowledge/suspicion that they may have been exposed to monkeypox or another STI in the past 14 days
    - Have had any newly diagnosed STI in the past 3 months, including gonorrhea, chlamydia, early syphilis, or HIV
    - Have attended an event (e.g., rave, sex party, sauna/bathhouse or other social venue), met sex partner(s) through online apps or social media platforms, or exchanged money or other goods/services for sex
    - Have a condition that may increase their risk for severe disease if infected with monkeypox virus, such as HIV or another condition that weakens their immune system, or they have a history of atopic dermatitis or eczema
    - Are on HIV pre-exposure prophylaxis (PrEP)
  - Individuals who report being a member of an exposed cohort (e.g., participated in activities associated with risk of transmission in a setting where multiple cases occurred)
  - Sex workers of any sexual orientation or gender identity
- **Priority 3 - PrEP:** Any individual not meeting the above criteria could be considered for PrEP. While the current vaccine supply does not allow for widespread vaccine use for PrEP; as demand for PEP and enhanced PEP has slowed down, administration of PrEP to reach individuals who may be at higher risk for acquiring

monkeypox, utilizing the following criteria is recommended. To reduce vaccine wastage, PrEP may be considered for other individuals (see details in vaccine administration section). As additional supply become available, further expansion of vaccine for PrEP will be considered.

- Gay, bisexual, or other men who have sex with men; transgender or gender diverse persons who have sex with men; and women who have sex with men who have sex with men AND one of the following:
  - have multiple (2+) or anonymous sex partners
  - may be at high risk for severe disease if exposed to monkeypox, such as individuals living with HIV or another immunocompromising condition
  - are on HIV PrEP
  - have had any newly diagnosed STI in the past 12 months, including gonorrhea, chlamydia, or syphilis
  - have recently (i.e., in the past 30 days) attended or plan to attend any venue where anonymous sex or sex with multiple partners will occur (e.g., saunas, bathhouses, sex clubs, sex parties, campgrounds) in the next 30 days
  - have met recent (i.e., in the past 30 days) partners with whom they had sexual or other intimate contact, or plan to meet partners with whom they will have sexual or other intimate contact in the in the next 30 days through social media platforms (such as Grindr, Tinder or Scruff), or at venues such as clubs, raves, sex parties, saunas, campgrounds etc.
  - are experiencing homelessness or housing insecurity
  - has been determined to be at high risk by a healthcare provider or public health official

Providers should prioritize and schedule second doses at the time of the first dose whenever possible. Providers should also contact individuals who received their first dose but do not have a second dose appointment scheduled in order to schedule one within the recommended interval. If an individual is beyond the recommended interval, a second dose should be scheduled as soon as possible, noting that if a person received one dose, a second dose can be administered without having to restart the series, even if the second dose is given after the minimum interval of four weeks. Providers are responsible for managing first and second doses from their supply and should not rely on a future shipment to accommodate second doses.

According to the U.S. Food and Drug Administration, Jynneos is indicated for prevention of smallpox and monkeypox disease in adults. However, since no vaccine is 100 percent effective, it is important for individuals to reduce their risk of potential exposures to monkeypox both before and after being vaccinated. We encourage vaccine providers to discuss [prevention strategies](#) with patients at the time of vaccination.

### **Vaccine Administration**

- Jynneos is **not** shipped from the SNS with ancillary supplies (syringes/needles); however, the Department will supply these through a separate process, unless the provider opts out.
- Jynneos is licensed as a series of two doses administered 28 days (4 weeks) apart.
  - The standard regimen for Jynneos involves a subcutaneous route of administration with an injection volume of 0.5mL. The standard regimen is the FDA-approved dosing regimen for individuals over the

age of 18. **Since August 9, 2022, the standard regimen has been authorized for people aged <18 years under an Emergency Use Authorization.**

- **In the context of the current national Public Health Emergency, and to stretch the limited resources, an alternative regimen should be used for people age ≥18 years under an Emergency Use Authorization beginning August 9, 2022. The authorized alternative regimen involves an intradermal (ID) route of administration with an injection volume of 0.1mL. CDC has noted that intradermal is the expected route of administration at this time,** noting that some individuals should not receive the vaccine intradermally, such as those who have a history of developing keloid scars.
- The second dose of Jynneos vaccine should be given 28 days after the first dose; however, based on available clinical study data and ACIP general best practices, the second dose may be administered up to four days before the minimum interval of 28 days and up to seven days later than the minimum interval or as soon as possible.
- 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.
- More information for providers is available and should be referenced in the CDC's [Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak | Monkeypox | Poxvirus | CDC](#) for more information regarding vaccine considerations and many related resources including:
  - Jynneos Package Insert
  - Jynneos Vaccine Information Statement (when given subcutaneously a VIS should be given to recipients; when given intradermally, a copy of the EUA should be given)
  - Jynneos Storage and Handling Summary
  - Jynneos Standing Orders (Standard and Alternative Regimen)
  - Jynneos Preparation and Administration Summary (Standard and Alternative Regimen)
  - Video and images for Administering Jynneos Intradermally
  - FDA EUA Fact Sheets for Providers and for Patients/Caregivers
  - Intradermal administration teaching tools.
- Healthcare providers are strongly encouraged, and in some cases required to report adverse events related to vaccine administration to the [Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](#)

The Department encourages strategies to minimize wastage of vaccine, understanding that this may not be possible in all circumstances and opportunities to vaccinate someone who needs it. Some examples of such strategies to maximize the use of thawed vials, or doses per vial, include but are not limited to:

1. coordinating the scheduling of several individuals for second dose appointments on the same day, which may mean scheduling clients up to four days before the recommended 28-day interval, or up to seven days (or as soon as possible) after the 28-day interval
2. maintaining a cancellation or waiting list and calling those clients to come in when an appointment opens up

3. when doses would otherwise go to waste, offering them to individuals who may not meet current eligibility criteria for PEP, enhanced PEP, or PrEP but may benefit from vaccination (e.g., health care workers involved in testing/treating patients suspected to have MPX)

### **Vaccine Administration Reporting**

Sites that administer monkeypox vaccine must report the vaccine administration in the following ways, in accordance with the Order of the Acting Secretary of Health:

- **Immunizations Information System (IIS):** All administrations of monkeypox vaccine from providers outside of Philadelphia must be recorded in PA-SIIS, following normal reporting requirements. All Administrations of monkeypox vaccine from providers within Philadelphia must be recorded in PhilaVax.
- **Monkeypox Vaccine Administration Reporting Form:** A supplemental form has been created to assist the Department in tracking utilization of vaccine, and to collect additional data points that may be required by CDC. This form should be filled out within 48 hours of vaccine administration and can be found at <https://bit.ly/PA-MPXvax>.

### **Vaccine Requests, Storage and Handling**

- Requests for vaccine doses to providers outside of a County Health jurisdiction should be sent to the Department who will take the lead on approving and coordinating vaccine transport.
  - Providers within county health departments should coordinate with that health department for vaccine access
- Vaccine must be kept in cold storage following proper storage and handling requirements.  
<https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf>

### **Additional Recommendations and Resources**

- **Co-infections with monkeypox and sexually transmitted infections (STI) have been reported (including acute HIV) therefore when someone presents as meeting eligibility criteria for vaccination, it is strongly recommended they be offered a comprehensive STD/HIV clinical evaluation, to include STD/HIV testing (including syphilis, chlamydia, gonorrhea, and HIV). It may also be a good opportunity to discuss HIV PrEP.**
- PA Health Alert Network (PA-HAN) - Healthcare providers can access the latest Health Alert Network notifications (HAN) on monkeypox (MPX) at [2022-HAN \(pa.gov\)](https://www.pa.gov/2022-HAN) If you do not receive PA-HAN notifications, sign up for the Pennsylvania Health Alert Network (PA HAN) at [Health Alert Network \(HAN\) \(pa.gov\)](https://www.pa.gov/HealthAlertNetwork)
- CDC [Clinician Outreach and Communication Activity \(COCA\)](https://www.cdc.gov/media/releases/2022/s0614-clinician-outreach.html) – COCA has provided a number of webinars regarding identification and treatment of monkeypox.
- [Vaccination Strategies | Monkeypox | Poxvirus | CDC](#)
- [PADOH Monkeypox Resource Page](#)
- [PADOH Monkeypox Virus Fact Sheet](#)