

Intradermal vaccination with JYNNEOS for adults, expansion of JYNNEOS eligibility criteria, guidance on pre-exposure prophylaxis for occupational risks, and guidance for minors.

Intradermal Vaccination with JYNNEOS for Adults

An emergency use authorization (EUA) has been issued by the U.S. Food and Drug Administration (FDA) for administering JYNNEOS vaccine via the intradermal (ID) route to eligible persons ages 18 years and older. Important information regarding implementing ID administration of JYNNEOS is outlined below.

[FDA has authorized intradermal \(ID\) administration of vaccine](#) to adults (18 years of age and older) as a dose-sparing policy that will allow up to five 0.1-mL doses to be administered from each 0.5-mL single-dose vial of JYNNEOS. [Guidance from the Centers for Disease Control and Prevention \(CDC\) endorses intradermal \(ID\) vaccination of adults against MPV.](#)

Supplies of JYNNEOS are expected to be limited throughout 2022. The number of doses available at the standard 0.5 mL volume are insufficient to protect prioritized populations at risk of contracting monkeypox (MPV) during the current epidemic. Therefore, ID dosing of JYNNEOS vaccine should be used for all eligible adults who are able to receive the vaccine via this route.

ID dosing of JYNNEOS (0.1 mL) was compared with subcutaneous (SC) dosing (0.5 mL) in a randomized trial of healthy adults aged 18-38 years. As [outlined by FDA](#) and published in [Vaccine](#), immune responses to 0.1-mL ID and 0.5-mL SC dosing were essentially identical.

By implementing ID dosing of JYNNEOS for all adults who are able to receive the vaccine by this route, Illinois is best able to progress rapidly with immunization of persons who fall under updated JYNNEOS eligibility criteria (see below).

Illinois sites receiving and administering JYNNEOS vaccine must shift to ID dosing for persons aged 18 years and older by Wednesday, September 7, 2022.

Sites must administer JYNNEOS by the ID route to those who are able to receive an ID dose, including persons with HIV and/or immune compromise, and may not offer patients the option of receiving an SC dose.

[Contraindications and precautions to JYNNEOS](#) apply to both ID and SC dosing routes.

Among adults without a contraindication to JYNNEOS, [only persons who have a history of developing keloid scars](#) may receive JYNNEOS by the SC route. Individuals of African, Asian, and Hispanic descent have higher rates of keloid development. Since most people across all races and ethnicities do not have a history of keloid formation, ask recipients individually about their history of forming keloids.

Illinois Department of Public Health

Illinois (outside of Chicago) providers that offer JYNNEOS must return the Illinois Department of Public Health (IDPH) MPV Provider Agreement prior to administering any doses of the vaccine. In addition, providers must sign the CDC MPV Provider Agreement prior to receiving each direct order or redistribution of vaccine.

Dose Reporting. IDPH will communicate directly with sites administering JYNNEOS about changes to utilization reporting that will accommodate both ID and SC doses.

Wastage Mitigation. JYNNEOS doses may be used only within eight hours after first puncture of the vial and any doses remaining after that time must be discarded.

All JYNNEOS recipients must meet the current Illinois Monkeypox Vaccine Eligibility Criteria (see below), without exception.

Strategies recommended to completely use all 0.1-mL doses in each vial include:

- Clustering vaccination visits in groups of five within eight-hour periods.
- Maintaining standby lists of persons who meet current Illinois monkeypox eligibility criteria and can be available to receive a dose on short notice.
- Initiating second dose scheduling to maximize utilization.
- Low dead-volume tuberculin syringes are recommended for the extraction of five 0.1-mL ID doses from JYNNEOS 0.5-mL vials. When regular tuberculin syringes are used, experience shows that it may be difficult to extract more than four full doses per vial. All air should be pushed out of the barrel of the empty syringe before entering the needle into the JYNNEOS vial. Partial or residual doses should not be combined from multiple vials to obtain a dose.

Immunization Technique. Since JYNNEOS vials contain no preservative, care should be taken to follow aseptic technique (perform hand hygiene before handling vials, clean vial stopper with alcohol before each puncture) and keep vaccine vials continuously at refrigerated temperatures (36-46°F) except when withdrawing doses.

Proper ID administration technique is important to minimize inadvertent underdosing, leakage from the injection site, or subcutaneous injection of vaccine that could reduce the level of immunity generated by a dose and require revaccination. See [CDC guidance for addressing errors and deviations](#) with JYNNEOS administration.

[Training resources](#) for proper administration of ID doses are available from CDC. Intradermal injection is a skill that requires training, practice, and competency evaluation for individuals who are not experienced in this technique. IDPH recognizes that some vaccinators may have difficulties with this technique and not every injection will be successful on the first attempt. Because intradermal injections are more difficult, clinic scheduling should allow vaccinators more time for each patient and avoid creating situations where vaccinators feel they are behind schedule and need to work more quickly. In addition, it is important that clinics establish a reporting culture whereby clinic providers feel safe from blame and, therefore, promptly report all errors and deviations. This will ensure each patient gets the proper dose of JYNNEOS and support systemic improvements related to injection quality and safety.

NOTE: FDA's recent EUA also allows persons ages 17 years of age and younger (no lower age limit) to receive JYNNEOS, but only by the SC route; ID administration is not authorized for minors. The SC dose to be administered is 0.5 mL regardless of age or weight.

Video Resources:

CDC Project Firstline multidose vaccine vial safety [video](#) (3:35 mins)

CDC JYNNEOS intradermal injection [video](#) (1 min)

2. Expansion of JYNNEOS Eligibility Criteria

CDC and IDPH recommend those who are highest risk for monkeypox get vaccinated with JYNNEOS as supply allows.

IDPH is coordinating with local health departments (LHDs) and providers to distribute vaccines. Additional supplies of JYNNEOS monkeypox vaccine and stretching of the available supply through use of ID vaccination are expected to increase vaccine availability this fall. Vaccination should expand to reach as many individuals at highest risk of monkeypox as possible to the extent permitted by limited supply.

Local health departments (LHDs) should:

- Expand the PEP++ approach as outlined below.
- Continue post-exposure prophylaxis (PEP) for persons known to be exposed to monkeypox.
- Continue pre-exposure prophylaxis (PrEP) for [occupational groups recommended for vaccination by ACIP](#).
- Consider vaccine equity when planning vaccination activities. Vaccines may be shared with medical providers and/or community-based organizations that can reach diverse populations at risk of monkeypox exposure.

In the setting of limited vaccine supply, for PEP ++, continue to prioritize first doses, when necessary, except for immunocompromised individuals, who should receive both doses on schedule.

Defer vaccination of individuals who have been diagnosed with monkeypox infection until further notice.

If vaccine doses are unused, local health jurisdictions should request to have a portion of their doses transferred to other local health departments in their region that need additional vaccine.

Populations to prioritize when vaccinating persons at high risk of exposure in the absence of a known exposure (PEP++).

Each local health jurisdiction should assess the unique circumstances within its respective jurisdiction. According to the PEP++ framework, individuals with risk factors that increase their likelihood for exposure in areas where monkeypox is spreading may be considered for vaccination, even if they have not had known exposure to someone with a confirmed or probable monkeypox infection. The following populations should be considered for PEP++ prioritization:

- All sexually active gay, bisexual, other men who have sex with men, and sexually active transgender, non-binary, or gender nonconforming individuals.

Among this group, individuals living with HIV (especially those who have a CD4 count < 200/mm³, are not virologically suppressed, or have an opportunistic infection) or other conditions that cause immunocompromise should be prioritized for vaccination, including second doses.

Efforts should be made to reach individuals who have barriers in accessing care, for example, engaging community organizations and trusted messengers for outreach and offering vaccines at non-clinical venues where individuals already attend (e.g., bathhouses, bars, clubs, pride events). In addition, colleges and universities should ensure that students who are eligible for vaccination are informed about local vaccine availability.

Venues to Consider for Vaccine Administration

When determining how and where to offer PEP++ (and PEP) vaccinations, consideration should be provided to locations that are acceptable and familiar to community members. Focused outreach, as opposed to open access, may ensure prioritized populations are more effectively reached. In non-urbanized areas, sites should be in discreet locations, whenever feasible.

Suggested venues include:

- STD and/or sexual health clinic sites.
- Lesbian, gay, bisexual, transgender, queer, and other (LGBTQ+) health clinics or community organizations.
- Sex-on-premises sites (e.g., saunas, bathhouses, sex clubs), in locations that are discreet yet distanced from primary areas of activity.
- Large events or venues, including pride events, where sexual activity may be more likely.
- Medical practices that provide focus on HIV care.
- Providers and/or medical practices that offer HIV PrEP.
- Local health jurisdiction clinics.
- Gyms, bars, or clubs that cater to communities at high risk.
- Other locations, as deemed appropriate by LHDs.

PEP Considerations

On August 11, 2022, CDC updated two guidance documents that contain PEP guidance: [Monitoring and Risk Assessment for Persons Exposed in the Community](#) and [Infection Prevention and Control of Monkeypox in Healthcare Settings](#). PEP continues to be available for individuals who have known close contact within the last 14 days with someone who tested positive for orthopoxvirus or monkeypox virus. Vaccination of close contacts of someone highly suspicious for monkeypox can also be considered while test results are pending.

PrEP Considerations

People who should get PrEP 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. Laboratory workers who handle blood, urine, and other specimens from patients with monkeypox for routine clinical testing are not included in this group.
- 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

At this time, most clinicians and laboratorians in the United States are not advised to receive monkeypox vaccine PrEP. Laboratorians should consult with laboratory biosafety officers and supervisors to identify risks and precautions, depending on the type of work they are doing. Regardless of whether they get PrEP, laboratorians should use recommended infection control practices.

Health care workers should be adequately protected from occupational monkeypox infection through proper use of [CDC recommended infection control practices](#). Infection control protocols for clinic staff collecting a monkeypox specimen (i.e., swabbing monkeypox lesion sites) include, but are not limited to, gown, eye protection, gloves, and N-95 respirator.

At this time, IDPH has not designated any health care and public health response team members to receive PrEP, except as noted above. LHDs and health care providers should consult with IDPH prior to making plans to vaccinate for this purpose to discuss available options and to help determine who would qualify to be designated to be part of a health care response team for orthopoxviruses.

Care of Minors Considerations

On August 9, 2022, the FDA issued an emergency use authorization (EUA) that allows for use of JYNNEOS in individuals younger than 18 years of age determined to be at high risk of monkeypox infection; in these individuals, JYNNEOS is administered by subcutaneous injection. Further details are in the Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-Replicating) for Prevention of Monkeypox Disease in Individuals Determined to be at High Risk for Monkeypox Infection. Minors will still require subcutaneous dosing with 0.5 ml of JYNNEOS rather than intradermal dosing.

Tecovirimat (TPOXX) is also available for use in individuals younger than 18 years of age, as CDC holds [a non-research Expanded Access Investigational New Drug \(EA-IND\) protocol](#) that allows for the use of tecovirimat (TPOXX) for primary or early empiric treatment of monkeypox, without age limitations.

VAERS

The vaccination provider is responsible for mandatory reporting of the following listed events following JYNNEOS to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors, whether or not associated with an adverse event.
- Serious adverse events* (irrespective of attribution to vaccination).
- Cases of cardiac events, including myocarditis and pericarditis.
- Cases of thromboembolic events and neurovascular events.

*Serious adverse events are defined as:

- Death.
- A life-threatening adverse event.
- Inpatient hospitalization or prolongation of existing hospitalization.
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
- A congenital anomaly/birth defect.

- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

For more information, see guidance in the [EUA Fact Sheet for Providers](#).

The EUA Fact Sheet for Recipients and Caregivers ([English](#)) ([Spanish](#)) should be provided when vaccinating persons younger than 18 years of age, or persons 18 years of age and older to whom the vaccine will be administered intradermally.

The [Vaccine Information Statement \(VIS\)](#) should be provided to individuals 18 years of age and older for whom JYNNEOS will be administered by the approved standard regimen.

[IDPH MPV Vaccine Provider Agreement](#)

IDPH has updated its MPV Vaccine Provider agreement to accommodate necessary changes based on the U.S. Department of Health and Human Services (HHS) Monkeypox Vaccination Program Provider Agreement. A blank copy is provided as an attachment to this SIREN. A new IDPH MPV Provider Agreement must be signed by LHDs and vaccinating providers, even if an older version is already on file with IDPH.

[HHS Monkeypox Vaccination Program Provider Agreement](#)

HHS has published a new Monkeypox Vaccine Program Provider Agreement that must be sent to providers with each order placed. A process for disseminating this document is under development. A copy of this agreement is attached to this SIREN.

Contact

IDPH Immunization Section, dph.immunizations@illinois.gov

Additional Resources

[JYNNEOS Package Insert](#)

[JYNNEOS Vaccine Information Statement \(VIS\)](#)

[JYNNEOS Vaccine Information Statement \(VIS\) in Spanish](#)

[JYNNEOS Storage and Handling Summary](#)

[JYNNEOS Standing Orders \(Standard Regimen\)](#)

[JYNNEOS Standing Orders \(Alternative Regimen\)](#)

[JYNNEOS Preparation and Administration Summary \(Standard Regimen\)](#)

[JYNNEOS Preparation and Administration Summary \(Alternative Regimen\)](#)

[Video: Administering JYNNEOS Intradermally](#)

[Images: Administering JYNNEOS Intradermally \[ZIP – 29 MB\]](#)

[ACAM 2000 Medication Guide](#)

[Vaccination Operational Planning Guide](#)

[FDA EUA Fact Sheet for Patients and Caregivers in Other Languages](#)

Monkeypox Vaccination Program Provider Agreement (Attached)

Target Audience

Local Health Departments, Infectious Disease Physicians

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September 2, 2022