Monkeypox (MPX) Vaccine FAQs for Providers & Local Health Departments

Updated 8/31/22 Note: MPX Vaccine Public FAQs already posted on the CDPH website. These FAQs are specifically for provider and LHJs. This document replaces the previous version on the LHJ SharePoint.

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MPX Vaccine Eligibility

Q: What options are available for MPX PEP or PrEP?
A: Two vaccines are available for PEP or PrEP:

- JYNNEOS: live, non-replicating vaccine; FDA-licensed for prevention of smallpox and MPX in people 18 years or older as well as under Emergency Use Authorization (EUA) for people under 18 years. Current supply is limited. JYNNEOS is approved as a series of two doses 28 days apart.
- ACAM2000: live, replicating vaccine containing vaccinia virus; FDA-licensed for prevention of smallpox.

At this time, CDPH is making JYNNEOS vaccine available for PEP and PrEP.

Q: Who should be offered MPX PrEP because they are at risk for occupational exposure?
A: CDC recommends MPX PrEP for people at risk for occupational exposure to orthopoxviruses. Current evidence shows that the risk for transmission of MPX to healthcare workers (HCWs) is low. While supplies of vaccine continue to be limited, CDPH recommends prioritizing vaccination to persons at risk in the community from their exposures outside of healthcare settings.

Current CDC infection control recommendations for healthcare facilities, including use of personal protective equipment (PPE), should be followed. PPE is readily available in healthcare facilities and is expected to be extremely effective at preventing transmission of MPX.
CDPH recommends ACIP guidance for vaccination of the following HCWs:

- Research laboratory personnel working with orthopoxviruses
- Clinical laboratory personnel performing diagnostic testing for orthopoxviruses
- Healthcare-worker response teams designated by appropriate public health and antiterror authorities.

At this time, clinicians in the United States and laboratorians not performing MPX testing are not advised to receive MPX PrEP. Healthcare providers who may have unusual exposures to MPX in the workplace should consult with their local health department about vaccination.

**Q: Who should be offered PEP after MPX exposure to a confirmed or probable case?**
A: Contacts to people with positive orthopoxvirus or MPX testing results (and contacts to high-suspicion cases awaiting laboratory results) may be eligible for PEP.

**Q: Who should be offered PEP after MPX exposure to a suspected case?**
A: PEP for contacts of highly suspected cases with pending orthopoxvirus testing results can be considered on a case-by-case basis.

**Q: What is the time window for offering MPX PEP?**
A: PEP can be given up to 14 days from the time of last exposure. PEP given within 4 days of the exposure may prevent onset of disease. PEP given 4-14 days after the exposure may reduce the symptoms of the disease but may not prevent the disease.

**Q: Should MPX PEP be given to symptomatic contacts of confirmed or probable cases?**
A: For contacts with symptoms suspicious for MPX infection (e.g., fever, rash), if testing is pending, it is reasonable to defer vaccination until test results are available; otherwise, PEP should be offered.

If symptoms are nonspecific (e.g., fatigue, mild respiratory symptoms without rash), offering PEP at the time of contact interview/testing maximizes the opportunity for prophylaxis and can be considered, especially if the contact is at risk for severe disease (under 8 years of age, pregnant, immunocompromised, history of atopic dermatitis or other exfoliative skin conditions).

Contacts with nonspecific symptoms (e.g., fatigue) may have an alternate diagnosis.

**Q: What are the benefits of MPX PEP/PrEP?**
A: PEP may prevent MPX disease if given within 4 days of exposure and may attenuate the severity of infection if given within 4-14 days of exposure.

PrEP can prevent MPX disease. Please refer to the FDA product inserts for a description of data used to establish vaccine effectiveness. Both JYNNEOS and ACAM2000 relied on antibody-based studies.

**Q: What are risks of MPX PEP or PrEP with JYNNEOS?**
A: Common adverse events include injection site reactions (pain/redness/swelling) and systemic adverse reactions (muscle pain, headache, fatigue). Serious adverse events are uncommon. Please refer to the JYNNEOS FDA Product Insert for full details.

**Q: What are contraindications and precautions to MPX PEP or PrEP with JYNNEOS?**
A:

- Severe allergic reaction (e.g., anaphylaxis) to a prior dose of JYNNEOS.
- People with a history of anaphylaxis to vaccine component (gentamicin, ciprofloxacin, egg protein) are considered to have a precaution to vaccination. Providers should discuss risks and benefits with potential recipients.

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1 It may be reasonable to consider PEP for certain exposures >14 days prior, such as high-risk exposure in a high-risk person at high risk for severe disease (Communication with Dr. Brett Petersen, CDC, 5/27/22)

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recipients. They may be vaccinated with a 30-minute observation period. Alternatively, taking into account the risk of acquiring MPX if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered.

- People of any age with a history of keloids should receive subcutaneous dosing of JYNNEOS.
- Please refer to the JYNNEOS FDA Product Insert for full details.
- Please refer to the CDC Table of Contraindications for JYNNEOS and ACAM2000 Vaccination.

Q: Should a person who had a previous smallpox vaccination still receive PEP or PrEP?
A: CDC recommends that those persons eligible for PEP and with a history of smallpox vaccination should receive a 2-dose JYNNEOS vaccine series. Those eligible for PrEP (or PEP++) due to potential non-occupational exposure and with a history of smallpox vaccination should also receive 2 doses of JYNNEOS.

Persons eligible for PrEP due to occupational exposure, as recommended by ACIP, and who have a history of smallpox vaccination are recommended to receive a single (1) JYNNEOS booster vaccine.

Ordering

Q: How can providers order JYNNEOS vaccine?
A: Healthcare providers should work with their local health department to obtain JYNNEOS vaccine.
- California Local Health Department Immunization Program Contact Information
- California Local Health Department Contact Information

Q: Where do I send my patients to get vaccinated?
A: MPX vaccine is available through local public health departments and some community providers. To find out where you may be able to get vaccinated, please contact your local health department.

Vaccine Eligibility in Specific Populations

Q: Can JYNNEOS be given to pregnant people? Can JYNNEOS be given to people who are breastfeeding?
A: Pregnancy and breastfeeding are not contraindications to immunization with JYNNEOS for persons exposed to MPX. Available human data on JYNNEOS administered to pregnant women are insufficient to inform vaccine associated risks in pregnancy. However, animal models, including rats and rabbits, have shown no evidence of harm to a developing fetus. MPX infection during pregnancy is associated with complications, including severe congenital infection, pregnancy loss, and maternal morbidity and mortality. Healthcare providers should discuss the risk and benefits with the patient using shared decision making.

Lactation is not a contraindication to immunization with JYNNEOS for persons exposed to MPX. It is unknown whether JYNNEOS is excreted in human milk. Data is not yet available to assess the effects of JYNNEOS in the breastfed infant or on milk production. However, because JYNNEOS vaccine is replication-deficient, it likely does not present a risk of transmission to breastfed infants. Healthcare providers should discuss the risk and benefits with the patient using shared decision making.

Pediatric Vaccination

Q: Can JYNNEOS vaccine be given to children under 18 years old?
A: JYNNEOS is licensed by the FDA for use in the prevention of MPX in people ages 18 years and older. Use in people under 18 years is available by emergency use authorization (EUA) from FDA and CDC for immunization by subcutaneous (SC) injection for prevention of MPX disease in individuals determined to be at high risk for MPX infection.
Q: Do parents need to consent for minors receiving JYNNEOS vaccine?
A: CDPH is unable to provide legal guidance regarding issues of parental consent for the administration of JYNNEOS to minors. We recommend that providers contact their counsel on this subject.

Vaccine Storage & Handling

Q: Where can I find detailed storage and handling information for JYNNEOS vaccine?
A: Providers may refer to CDC’s JYNNEOS storage & handling guidance.

Q: How long can JYNNEOS vaccine be stored refrigerated 2°C to 8°C (36°F to 46°F) after thawing?
A: 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.

Q: How long can JYNNEOS vaccine be stored at room temperature 8°C to 25°C (46°F to 77°F)?
A: Unpunctured vials may be held at room temperature for up to 6 cumulative hours.

Q: Once the vaccine has been drawn up in syringes, can those pre-drawn syringes be stored in refrigerated temperatures for up to 8 hours?
A: Best practices do not support prolonged time in syringes prior to administration.

General Vaccine Administration

Q: Can doses from two vials be combined into a single shot?
A: No

Q: What if I can’t get 5 doses per vial?
A: There has been variation in the ability to draw 5 doses per vial (ranging from 3-5) depending on technique and supplies used.

Q: Who can administer JYNNEOS vaccine?
A: Physicians, nurses, and other qualified healthcare professionals may administer JYNNEOS vaccine. Please refer to Authorized Licensees and the Emergency Medical Services Authority letter in response to the Governor’s Emergency Declaration.

Q: When should someone get their second dose of JYNNEOS vaccine?
A: JYNNEOS is licensed by FDA for a 2-dose series given at an interval of 28-days. Per CDC guidance, a dose given 4 days early is considered valid (24 days after the first dose). If the second dose is administered beyond 28 days, the first dose does not need to be repeated. If the first dose is administered subcutaneous, the second dose may be administered intradermal or subcutaneous. California released guidance on 7/27/22 related to prioritization of doses for first or second doses.

Q: What is the vaccine effectiveness for the JYNNEOS vaccine?
A: JYNNEOS is approved for the prevention of MPX disease in individuals 18 years of age and older at high risk for MPX infection. Licensure was supported by animal studies as well as clinical studies demonstrating a comparable immune response to ACAM2000 (Rao AK et al, MMWR, 2022; 71(22):734-742). No immune correlate of protection (i.e., minimum threshold level of antibodies needed to prevent symptoms) has been established.

One peer-reviewed study of 524 randomized subjects found that immunogenicity was non-inferior following the alternative regimen (intradermal) versus the standard regimen (subcutaneous) (Frey SE et al, Vaccine, 2015; 33(39):5225-5234). This study supported the authorization of the alternative dosing regimen for people 18 years of age and older.
Q: Where can I find standing orders for JYNNEOS vaccine?
A:

- Preferred – Alternative Dosing Regimen (intradermal): [link](#)
- Standard Regimen (subcutaneous): [link](#)

**Intradermal Vaccine Administration**

**Q: Who should get intradermal dosing of JYNNEOS vaccine?**
A: CDC and CDPH recommend intradermal administration for all eligible populations. In addition, special populations eligible for intradermal dosing include people with prior history of small vaccination, people who are pregnant or breastfeeding, people with three or more major cardiac risk factors, and people with atopic dermatitis, eczema, or other exfoliative skin conditions. Please see current CDC guidance for more information.

**Q: How do I administer JYNNEOS vaccine intradermally?**
A: Under new guidance, JYNNEOS vaccine can be administered through intradermal (ID) injection for people ages 8 years and older. The authorized alternative regimen involves an injection volume of 0.1mL.

When administering JYNNEOS vaccine, the preferred location is the volar (inner aspect) of the forearm. If an alternate site is needed (significant scarring; amputee), can consider the upper back below the scapula.

For specific technical guidance related to MPX vaccine, please refer to the [EZIZ MPX page](#), which includes links to CDC MPX vaccine clinical guidance, storage and handling, and vaccine administration details. A video on intradermal technique can be found [here](#).

**Q: What about tattoos?**
A: Avoid tattoos under 1 month old and pigmented areas of older tattoos; if unable to do so, administer vaccines through the tattoo.

**Q: What kind of syringes should be used for intradermal administration?**
A: The intradermal dosing regimen supported through the Emergency Use Authorization does not specify a syringe/needle type and thus, any commercially available needle/syringe combination that would allow intradermal use would be acceptable. CDC administration guidance currently mentions use of a 26- or 27-gauge x 3/8”, 1/4” to 1/2” needle with a short bevel as an example and not a requirement.

**Q: What about pre-filled/pre-drawn syringes (e.g., for mass vaccination events)?**
A: Not recommended. Currently no data available on viability or storage for this method.

**Subcutaneous Vaccine Administration**

**Q: Who should get subcutaneous dosing of JYNNEOS vaccine?**
A: Individuals of any age with a history of developing keloid scars and individuals younger than 18 years of age.

**Q: How do I administer JYNNEOS vaccine subcutaneously?**
A: The standard regimen involves a subcutaneous (SC) route of administration with an injection volume of 0.5mL. The standard regimen has been approved for people aged 18 years and older, as well as authorized for people aged less than 18 years under an Emergency Use Authorization.

**Q: Is there a lower age limit for JYNNEOS vaccine?**
A: There is currently no established lower age limit for JYNNEOS vaccine.
### Reporting

**Q:** What are major reporting requirements for providers who administer JYNNEOS vaccine?  
**A:** Providers should report doses to their immunization registry within 24 hours of vaccine administration.

**Q:** Where should providers report adverse events following vaccination?  
**A:** Adverse events that occur in a recipient following MPX vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting is encouraged for any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Vaccine administration errors can be reported whether or not associated with an adverse event. Information on how to submit a report to VAERS is available at [https://vaers.hhs.gov](https://vaers.hhs.gov) or by calling 1-800-822-7967.

### Billing & Reimbursement

**Q:** Where can JYNNEOS vaccine providers find current information and resources on vaccine billing and reimbursement?  
**A:** Providers can refer to following resources:

- DHCS MPX Services and Reimbursement for FQHC, RHC, IHS-MOA and Tribal FQHC Providers
- DHCS “Coming Soon: MPX Vaccines as Medi-Cal Benefit”

**Q:** Can providers bill for JYNNEOS vaccine?  
**A:** There would be no cost for the vaccine itself as it is provided by the United States Government. Providers may charge an associated administration fee (or facility fees). Providers should bill for MPX vaccine administration using the same processes they use for other routine vaccines (e.g., Tdap and MMR).

- Providers can use the ICD-10 Z code, “Z23 Encounter for immunization”, and they could consider offering MenACWY or other recommended vaccines at the same time and bill for them concurrently.
- ICD-10 codes should be available for orthopoxvirus infections.

### Communication Resources

**Q:** Where can I stay informed on MPX vaccine information?  
**A:** The [CDPH MPX Page](https://www.cdph.ca.gov/Programs/QAP/MPXVaccine/Pages/default.aspx) has information for the public, providers, and local health departments. For specific technical guidance related to MPX vaccine, please refer to the [EZIZ MPX page](https://eziz.medicalexperience.com/mpxvaccine).

**Q:** Where can I access MPX vaccination data dashboards?  
**A:** The [CDPH MPX Page](https://www.cdph.ca.gov/Programs/QAP/MPXVaccine/Pages/default.aspx) has information on MPX vaccine allocations and other MPX data.

### Additional Resources

[CDC Clinician FAQs](https://www.cdc.gov/ovs/advisory-committees/mammals/mammals-faqs.html) include frequently asked questions and answers on these topics:

- [Vaccination Schedule and Use](https://www.cdc.gov/vaccines/schedules/downloads/adult/adult sched.pdf)
- [Who is Eligible](https://www.cdc.gov/vaccines/schedules/downloads/adult/adult sched.pdf)
- [Vaccination Dosage and Administration](https://www.cdc.gov/vaccines/schedules/downloads/adult/adult sched.pdf)
- [Vaccine Safety](https://www.cdc.gov/vaccines/schedules/downloads/adult/adult sched.pdf)
- [Vaccination and MPX Infection](https://www.cdc.gov/vaccines/schedules/downloads/adult/adult sched.pdf)