

Los Angeles County Public Health's Guidance for Healthcare Providers and Contractors Administering JYNNEOS Vaccine to Minor Patients

September 2022

Los Angeles County Department of Public Health (Public Health) is sharing this Guidance to promote the health and safety, general welfare, and effective patient care related to the provision of monkeypox healthcare for minors during the current monkeypox outbreak. Please be aware that as the monkeypox emergency continues, recommendations and authorizations concerning treatment and prevention of monkeypox, including to minors, may change without notice. This includes recommendations on testing, vaccine administration and antiviral treatment. This Guidance was developed for use by Public Health affiliated healthcare providers based on federal, state, and local laws and regulations, and federal Public Health Emergency Declarations (Los Angeles County Department of Public Health, State of California, and U.S. Department of Health & Human Services). Providers should consult FDA and CDC guidelines for the current authorizations and recommendations, as well as applicable federal, state, and local laws. Providers should also consult with their Health & Safety, Infection Control, Risk Management, and Counsel before deciding to use or rely on any of the information or processes in this Guidance. Any decision to use all or part of this Guidance rests solely with the provider. In making this Guidance publicly available, Public Health is not assuming or imposing any obligation for which it may be liable. This guidance will be posted on www.lacounty.publichealth.com.

Background

Monkeypox is a disease caused by infection with the monkeypox virus, an orthopoxvirus transmitted between persons through close skin to skin contact. The current outbreak started in May 2022. On August 2, 2022, the Los Angeles Board of Supervisors ratified a local emergency declaration in response to the current monkeypox outbreak. The State of California declared a State of Emergency on August 1, 2022, and the federal government declared a public health emergency on August 4, 2022. Although monkeypox disease during this outbreak has not been associated with high fatality rates, many have suffered extensive and painful skin lesions on their body including anorectal and oropharyngeal lesions that are debilitating.

In California, adolescents (ages 12-17 years old) can legally consent to receiving healthcare related to their sexual health, or in relation to reportable infectious diseases like monkeypox during an outbreak. Currently, minors 12-17 years can consent to receive HPV and Hepatitis B vaccine and similar to monkeypox, both of these infections can be transmitted through non-sexual routes including vertical transmission, household contacts, and sharing needles. Allowing widespread access to vaccination in all at-risk populations is critical to this outbreak response, to promoting public health and to preventing further disease transmission. Public Health issues this guidance to its

healthcare providers and contractors administering monkeypox vaccine to promote public health and to prevent further disease transmission.

Guidance

1) On August 9, 2022, the U.S. Food and Drug Administration (“FDA”) issued an Emergency Use Authorization (“EUA”) for use of JYNNEOS vaccine for the prevention of monkeypox disease in individuals determined to be at high risk of monkeypox infection. The EUA does not require informed consent for persons of any age other than general consent for medical care.

2) A minor is defined as an individual under 18 years of age.

3) Generally, a parent or guardian’s consent is required for the provision of healthcare for a minor, including vaccinations, except under certain limited circumstances. These circumstances include:

a) Minors ages 12–17 years who are seeking medical care related to the prevention of a sexually transmitted disease. (California Family Code § 6926(b)).

b) Minors ages 12-17 years who may have come into contact with an infectious, contagious, or communicable disease that is reportable to the Health Officer, which includes outbreaks such as the current monkeypox outbreak, and are seeking medical care related to the diagnosis or treatment of that disease. (California Family Code § 6926(a)).

c) Self-sufficient minors defined as: age at least 15 years; living separate and apart from the minor’s parents or legal guardian (regardless of consent of parents/guardian or duration of separate residence); and managing the minor’s own financial affairs (regardless of source of income). (California Family Code § 6922).

d) Emancipated minors defined as: a minor who is legally married/established domestic partnership; on active duty in the U.S. armed forces; or has a court-issued Declaration of Emancipation. (California Family Code §§ 7002, 7050).

4) In the limited circumstances outlined above where (a) a minor can consent to medical treatment without the parent or guardian’s consent, (b) the minor in fact consents, and (c) the minor has not requested the parent or guardian be treated as a personal representative or otherwise consented to sharing the information with the parent, then Public Health affiliated providers must treat the medical records associated with that treatment and information about the care as confidential and must not disclose the records or information to the parent or guardian unless the minor consents to such disclosure. (42 C.F.R. § 164.502(g)(3)); California Health & Safety Code §§ 123110, 123115).

5) Vaccination providers must provide the Vaccine Information Fact Sheet for Recipients and Caregivers (“Fact Sheet”) to all vaccine recipients or their caregiver. For minor patients ages 12-17 years who are consenting for their own care, Public Health -

affiliated providers should provide the Fact Sheet to the consenting minor, and to their parent or guardian only if the minor consents to release information to the parent or guardian. Providers shall follow their standard processes to document the minor's consent while maintaining confidentiality. Providers may distribute the Fact Sheet or a link to the Fact Sheet.

6) Public Health-affiliated providers must document that the Fact Sheet was provided.

7) If a minor who can consent to the care wants to have their parent or guardian consent to the care, best practice is to have both the minor and the parent or guardian consent.

8) For any minor who is not authorized to consent for the care (e.g., age under 12, unable to understand risks and benefits of medical care, etc.), their parent or other guardian holding legal authority to consent to medical care may consent for the minor.

Q&A About Minor Consent for Healthcare Related to Monkeypox

1) Is monkeypox related care considered sexual health care?

a) Monkeypox is transmitted through direct skin-to-skin contact, including sexual contact. Therefore, even though it is not exclusively a sexually transmitted infection and can spread by any close, skin-to-skin contact, it can be considered a sexually transmissible disease and the Health Officer considers medical care related to the prevention of monkeypox as part of general sexual health care.

2) Can a minor get treatment or vaccine if they are not sexually active?

a) Yes, as summarized above, a minor age 12 or older can receive medical care related to the diagnosis or treatment of monkeypox either with or without their parent/guardian because it is a communicable disease reportable to the Health Officer. A provider should refer to Los Angeles County Vaccine Eligibility which will be updated based on vaccine supply, advancements in data, and local outbreak conditions.

3) How should a provider or clinic care maintain confidentiality for a minor if they are consenting to care without their parent or guardian?

a) A provider must treat the minor's records and information about the care as confidential unless the minor consents to disclosing the records or information to the parent or guardian. The provider must utilize all the tools available to maintain the privacy of the minor including, but not limited to: documenting a confidential phone number to contact the patient, refraining from using automatic text/email reminders for confidential clinic visits (including future care, such as second shot), identifying clinical notes and lab results as "confidential" in the medical record so they are not released without the minor's consent, not discussing confidential care when a parent or other person is present.

4) How does confidentiality for the provision of monkeypox related healthcare for minors relate to mandated reporting laws?

a) All existing mandated reporting laws still apply separate from the confidentiality rules related to sexual health care and monkeypox related care for minors. Mandated reporters must make reports whenever required by law. Patients should be counseled about those limitations on confidentiality and providers should follow their institutional policies around mandating reporting.

b) While clinics serving adolescents may be experienced in mandated reporting and confidentiality protection, other locations, such as mass vaccination sites, should ensure staff are fully trained and aware of mandated reporting and confidentiality requirements for minors.

5) Is the JYNNEOS vaccination status of a minor available in California Immunization Registry (CAIR)? Could a parent or other person with access to CAIR or other vaccination record see that a minor has been vaccinated?

a) Yes, currently all JYNNEOS vaccines that are administered are reported to CDPH and available for view to those with access to CAIR. Providers must counsel minor patients that other entities (e.g., schools or parents) may have access to the minor's vaccination record without the minor's explicit consent. In particular, there is a concern that many schools get automatic access to the minor's vaccination records through this avenue, and that could result in the school having a record of certain vaccinations (like the JYNNEOS vaccine or HPV vaccine) that could be accessed by parents through the minor's school.

b) There is an 'opt-out' process in CAIR, where a minor can lock their vaccination records. Providers should be aware that if a minor chooses the opt-out process, it is not limited to just JYNNEOS vaccine. Institutions, such as schools, will not be allowed to see any vaccinations but could be seen by parents and guardians. i. To initiate the 'opt-out' process, follow the instructions under CAIR Sharing Policy.