DAVID Y. IGE
GOVERNOR OF HAWAII

ELIZABETH A. CHAR, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HI 96801-3378

In reply, please refer to:
File:

August 15, 2022

MEDICAL ADVISORY: UPDATE—MONKEYPOX VIRUS VACCINATION RECOMMENDATIONS

- DOH is expanding eligibility criteria for JYNNEOS vaccine to include post-exposure prophylaxis (PEP), expanded post-exposure prophylaxis (PEP++), pre-exposure prophylaxis (PrEP), and second doses.
- Intradermal administration of JYNNEOS is recommended over subcutaneous administration for eligible adults 18 and over who do not have contraindications to intradermal administration.
- JYNNEOS is available under FDA emergency use authorization (EUA) to children and adolescents less than 18 years of age. Only subcutaneous administration is approved for this age group.

Dear Healthcare Provider:

As of August 15, 2022, the Centers for Disease Control and Prevention (CDC) reported a total of 11,890 confirmed monkeypox/orthopoxvirus cases in the United States. As of August 15, 16 monkeypox cases have been diagnosed in Hawaii. Among the 14 cases with available epidemiological data, 13 were among Hawaii residents, and 6 (43%) had exposure related to travel outside of the state. Many but not all of the cases reported nationally have been among gay, bisexual and other men who have sex with men. According to a recent CDC Morbidity and Mortality Weekly Report, 70% of cases reported two or more sexual partners within the 3 weeks preceding symptom onset.

On August 9, the White House announced an updated national vaccination strategy to prevent spread of monkeypox virus infection among affected populations. Based on evidence of similar immunogenicity of a smaller volume intradermal dose compared with subcutaneous administration routes, and in order to make JYNNEOS more broadly available for PEP, PEP++, and PrEP including second doses to complete the recommended two dose series, intradermal administration is now recommended over subcutaneous administration for eligible adults who do not have a contraindication to intradermal administration.

Expanded DOH Eligibility Criteria for JYNNEOS Vaccine
Based on the new national guidance, EUA approval of JYNNEOS administration by the intradermal route, available vaccine supply, and assessment of known risk factors for monkeypox virus infection, DOH is expanding JYNNEOS eligibility criteria beyond PEP and PEP++ to include pre-exposure prophylaxis (PrEP) for groups at increased risk of exposure. Updated eligibility criteria are as follows:

- Close contact in the last 14 days with a person with known or suspected monkeypox infection
- Gay, bisexual, and other men who have sex with men (MSM) and transgender individuals who have multiple or anonymous sex partners (e.g., such as through dating apps)
- Persons with severe immune compromise (e.g., advanced or poorly controlled HIV infection [CD4 ≤200 cells/mm3, persistent HIV viral load >200 copies/mL, or a recent HIV-related illness], active cancer treatment, high-dose steroids) or certain skin conditions, such as eczema, AND who have a household member or sex partner at high risk for monkeypox
- People in certain occupational risk groups[1]

Second Doses of JYNNEOS

- For PrEP, two doses of JYNNEOS are recommended with the second dose administered 28 days after the initial dose.
- Individuals who received a first dose of JYNNEOS for PEP or PEP++, but have not yet received a second dose, should receive a second dose 28 days after their first dose, or as soon as feasible if 28 days have already passed since their first dose.

Intradermal Administration of JYNNEOS

JYNNEOS is now authorized via a FDA EUA for intradermal administration for the prevention of monkeypox in individuals 18 years of age and older when two 0.1 ml doses are administered 4 weeks apart. A completed phase 2 trial demonstrated nearly identical immunogenicity between the 0.5 ml SC and 0.1 ml ID dosing and administration routes and serves as the basis for this authorization.

Intradermal administration involves injecting the vaccine superficially between the epidermis and hypodermis layers of the skin, typically of the volar aspect of the forearm. This should produce a noticeable wheal. People who have a history of developing keloid scars should be administered JYNNEOS by subcutaneous injection.

A history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS is a contraindication for vaccination. Intradermal vaccination with JYNNEOS has been associated with increased reports of local injection site redness, itching and swelling compared with subcutaneous administration. Patients should be informed of this side effect of intradermal vaccination.

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. CDC has provided updated interim guidance for the use of JYNNEOS vaccination for the prevention of monkeypox infection.

[1] People at risk for occupational exposure to orthopoxviruses include research laboratory workers performing diagnostic testing for Monkeypox virus, and members of health care worker response teams designated by appropriate public health and antiterror authorities (see ACIP recommendations).

HDOH clinics scheduled on or after August 20, 2022 will be administering JYNNEOS vaccine by the intradermal route. HDOH is working with clinical partners providing JYNNEOS vaccination to provide training on intradermal injection and to address other logistical considerations in switching from subcutaneous to intradermal administration. Partner sites are encouraged to transition to intradermal administration as the primary administration route as soon as possible to ensure equitable access to PrEP across the state.

Emergency Use Authorization of JYNNEOS for Pediatric Populations
The FDA EUA authorizes subcutaneous administration of two doses (0.5 mL each) of JYNNEOS to individuals younger than 18 years of age based on available JYNNEOS safety and immunogenicity data in adults as well as the historical data with use of live vaccinia virus smallpox vaccine in pediatric populations.

Where to Refer Patients Eligible for JYNNEOS
Individuals eligible for vaccination may arrange for vaccination by contacting:

Provider/Organization	Area Served
Hawaii Department of Health Phone: (808) 586-4462 Online: health.hawaii.gov/docd/mpxvax	Statewide
Hawaii Department of Health Kauai District Health Office (808) 241-3495	Kauai
Malama I Ke Ola Phone: (808) 871-7772	Maui
Waianae Cost Comprehensive Health Center Phone: (808) 427-0442	O‘ahu (sites in Waianae and Kapolei)
Hawaii Health & Harm Reduction Center Phone: (808) 521-2437	O‘ahu (site in Honolulu)

DOH will update the list of providers online at health.hawaii.gov/monkeypox as additional providers are able to provide vaccination.

We greatly appreciate your efforts to help protect Hawaii’s population during this ongoing monkeypox outbreak.

Sincerely,

Sarah K. Kemble, M.D.
State Epidemiologist

Monkeypox is considered an **URGENTLY REPORTABLE** condition. Providers should notify HDOH immediately of all clinically suspected cases and of persons with a positive laboratory test for orthopoxvirus by contacting one of the numbers below. Laboratories are required to report positive test results for orthopoxvirus through electronic laboratory reporting within 24 hours of test completion.

Oahu (Disease Reporting Line) .....(808) 586-4586
Maui District Health Office.....(808) 984-8213
Kauai District Health Office.....(808) 241-3563
Big Island District Health Office (Hilo).....(808) 933-0912
Big Island District Health Office (Kona) .....(808) 322-4877
After hours on Oahu .....(808) 566-5049
After hours on neighbor islands .....(800) 360-2575 (toll free)

Additional Resources:

CDC JYNNEOS interim guidance: https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#interim

Jynneos EUA review memo 08092022; https://www.fda.gov/media/160785/download

FDA EUA for intradermal adminstration: https://www.fda.gov/media/160784/download

FDA EUA Fact Sheet for Providers: https://www.fda.gov/media/160774/download

FDA EUA Fact Sheet for Patients and Caregivers: https://www.fda.gov/media/160773/download

JYNNEOS Package Insert: https://www.fda.gov/media/131078/download