Requirements at a Glance

Monkeypox (mpox) Vaccine

This guide summarizes mpox program requirements and operational guidance for local health departments (LHDs) and providers. It also identifies any differences from the COVID-19 Vaccination Program. **Note:** "Provider" may refer to clinics, practices, MCEs, hospitals, jails, and other state agencies that administer mpox vaccine. Summary guidance includes:

- Clinical & Operational Requirements
- Vaccine Management
- Vaccine Administration
- Billing & Reimbursement
- Suspension, Termination, Fraud and Abuse

For mpox vaccination resources, refer to CDPH's Mpox Webpage and Mpox Vaccination Resources (EZIZ).

Questions? Providers should contact their local health department. LHDs may contact CDPH using the appropriate vaccine inboxes.

Topic	Requirements & Guidance	Resource Links
	Clinical & Operational Requirements	
Provider Agreement	*With use of the JYNNEOS™ vaccine provided at no cost by the US government, the provider and provider's organization will be deemed to have agreed to comply with the requirements of this Agreement. Any person accessing this vaccine is subject to compliance with the terms of this Agreement. (Mpox Provider Agreement)* *Organization must monitor this Agreement website for updates and comply with any such posted updates. (P.A. #2)*	• Mpox Provider Agreement (CDC & HHS)
ACIP, CDC & FDA Requirements & Recommendations	*Organization must administer JYNNEOS in accordance with all relevant requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP) (including those in the CDC Interim Clinical Considerations for Mpox Vaccination and any CDC Emergency Use*	• Interim Clinical Considerations for

Topic	Requirements & Guidance	Resource Links
	Instructions as they may be revised from time to time), and consistent with the scope of the Food and Drug Administration's (FDA's) approval, authorization, and/or any applicable expanded access requirements per FDA's protocol. (HHS MPOX Provider Agreement #1)	• Mpox Vaccination (CDC) • JYNNEOS Fact Sheet for HCPs (FDA)
	LHDs and Providers: Similar requirement as for COVID-19.	
Vaccination Services	*Organization's vaccination services must be conducted in compliance with these items (P.A. #12):* a. *All applicable local, state, and federal vaccination laws* b. *CDC's guidance on vaccine administration* c. *CDC's General Best Practice Guidelines for Immunization*	• Vaccine Administration (CDC) • General Best Practice Guidelines for Immunization (CDC)
	LHDs and Providers: Similar requirement as for COVID-19.	
Record Keeping	*Organization must make records related to participation in the HHS Mpox Vaccination Program available for immediate inspection upon request by HHS, its relevant component agencies, and relevant state, tribal, territorial, or local public health authorities. (P.A. #9)* *Organization must preserve all records related to JYNNEOS vaccine management and administration for a minimum of 3 years, or longer if required by state, local, or territorial law. (P.A. #10e)*	
	LHDs and Providers: Similar requirement as for COVID-19.	
	Vaccine Management	
Ordering Vaccine	**Providers:** Providers that have received an mpox order or transfer have been marked with an active "Outbreak" program and are eligible to order vaccine. If your location has been marked as eligible, you can now **place direct orders** in myCAvax using the "New Vaccine Order" screen. **LHDs:** Local Health Departments (LHDs) can mark providers eligible to order mpox vaccine through myCAvax by activating the "Outbreak" program for the provider location. CDPH plans on notifying providers to contact their LHD for activation if they are interested in ordering mpox vaccine. LHDs may contact the COVID-19 Provider Call Center for assistance activating provider locations.	

Topic	Requirements & Guidance	Resource Links
	The COVID-19 Vaccine Ordering team monitors mpox vaccine orders to add virtual inventory as needed in myCAvax. Please reach out to the COVID-19 Call Center at COVIDcallcenter@cdph.ca.gov or via Chatter @Ordering Leads regarding vaccine ordering and allocations. For all other inquiries, please contact the mpox vaccine team at mpoxvaccine@cdph.ca.gov	
Receiving & Storing Vaccines	*Organization must store and handle JYNNEOS vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with CDC guidance regarding Mpox vaccines in the CDC Vaccine Storage and Handling Toolkit Addendum.*	• Vaccine Storage and Handling Toolkit & Addendum (CDC) • EUA Fact Sheet for HCPs (FDA)
	Providers: Providers do not receive MPOX vaccine shipments. **LHDs:** Receive MPOX vaccine shipments from the state's EPO Warehouse and transfer to your providers as needed. For JYNNEOS receiving and storage guidance, *CDC Vaccine Storage and Handling Toolkit Addendum*.	
Reporting Shipment Incidents	**Do not report MPOX shipment incidents in myCAvax. Report vials—not doses—when reporting order discrepancies.** **Providers:** Providers do not report MPOX vaccine shipment incidents. **LHDs:** Email RSSUser32@cdph.ca.gov (EPO Warehouse) for resolution.	
Temperature Monitoring	*Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance located in CDC Vaccine Storage and Handling Toolkit Addendum.*	• Vaccine Storage and Handling Toolkit (CDC) • COVID-19 Temperature Log
	LHDs and Providers: Monitor and record temperatures daily (twice daily if storing MPOX and COVID-19 vaccines in the same storage unit). May use the same temperature log used for COVID-19 vaccines.	
Reporting Temperature Excursions (Out-of-Range Temperatures)	*Organization must comply with CDC Vaccine Storage and Handling Toolkit Addendum guidance for dealing with temperature excursions. (P.A. #10c)*	• Vaccine Storage and Handling Toolkit (CDC)
	Do not report MPOX temperature excursions in myCAvax. Report vials—not doses—when reporting spoiled vaccine.	

Topic	Requirements & Guidance	Resource Links
	LHDs and Providers: Email RSSUser32@cdph.ca.gov (or follow your LHD reporting process if different) for resolution.	
Managing Expiration and Beyond-Use Dates	*Organization must monitor and comply with vaccine expiration dates and beyond-use date timeframes per CDC Vaccine Storage and Handling Toolkit Addendum.*	• Vaccine Storage and Handling Toolkit (CDC)
	LHDs and Providers: Similar requirement as for COVID-19.	
Reporting Inventory	*Organization must report weekly the number of doses of JYNNEOS vaccine that were administered, remain in inventory, or were spoiled, expired, or wasted during the previous week. These reports of inventory count and aggregate doses administered must be submitted by the Organization through the IIS. Future allotments of this vaccine are dependent upon Organization reporting of Vaccine Administration Data and reporting required under this paragraph. (P.A. #8)*	
	Do not report MPOX inventory to VaccineFinder. **LHDs and Providers:** CDPH will calculate and report mpox inventory to CDC based on provider reporting of doses administered and wasted; reporting requirements may change in the future to meet federal requirements. Please be sure to report doses administered and wasted to help ensure accurate data.	
Reporting Wastage	*Organization must report weekly the number of doses of JYNNEOS vaccine that were administered, remain in inventory, or were spoiled, expired, or wasted during the previous week. These reports of inventory count and aggregate doses administered must be submitted by the Organization through the IIS. Future allotments of this vaccine are dependent upon Organization reporting of Vaccine Administration Data and reporting required under this paragraph. (P.A. #8)*	Mpox reporting spreadsheet (non-COVID providers)
	Report MPOX wastage in vials—not doses. Do not report if *any* doses are administered; else report vial as wasted. *Important:* Report spoiled expired and wasted vaccine as soon as possible but no later than weekly for the previous week. CDPH uses this data to calculate and report inventory to CDC. If using myCAvax to report, field name may display "Doses" but enter the number of vials. **COVID Providers:** Report in myCAvax as for COVID-19.	

Topic	Requirements & Guidance	Resource Links
	For non-COVID Providers: Report to your LHD per existing protocols (or download and email mpox reporting spreadsheet to your LHD). **LHDs:** Use "New Waste Report" admin form in myCAvax to report your wastage and for any non-COVID providers. Work with any non-COVID providers in your jurisdiction to aggregate their data.	
Vaccine Transfer	*Organization is prohibited from transferring JYNNEOS vaccine doses to another provider unless authorized by HHS or the relevant public health jurisdiction. (P.A. #13)*	
	Providers: Unlike for COVID-19, providers must contact their LHD *prior* to any emergency/unplanned transfer (e.g., unable to use short-dated vaccine before expiration). **LHDs:** Transfer vaccine as needed from providers who can't use short-dated vaccine before expiration or who are suddenly short vaccine.	
Reporting Vaccine Transfer Events	**Report MPOX vaccine in vials—not doses—and within 24 hours of the event.** In myCAvax, field name may display "Doses" but enter the number of vials. **Providers and LHDs:** Use "Redistribution/Transfer" button in myCAvax to record events.	
	Vaccine Administration	
Vaccine Administration & Allocations	*The JYNNEOS vaccine may be administered subcutaneously using the standard regimen (subcutaneous route (PDF)) or intradermally (intradermal route (PDF)). People of any age with a history of developing keloid scars and individuals younger than 18 years of age should receive the vaccine via the subcutaneous route. Patients with concerns about intradermal administration due to potential stigma or other personal reasons should be offered subcutaneous doses. CDC recommends that health care providers have both subcutaneous and intradermal vaccine administration options available on site, so patients choose their preferred route of administration. An updated California Department of Public Health (CDPH) JYNNEOS vaccine screening (PDF) checklist (also available in Spanish (PDF)) can be used to check for a history of keloids.*	• EUA Fact Sheet for HCPs (FDA) • Standard Regimen Preparation and Administration Summary - Subcutaneous Administration (CDC)

Topic	Requirements & Guidance	Resource Links
	Applies to LHDs and Providers. ***Administration:*** 0.1mL per injection for the intradermal route, 0.5mL per injection for the subcutaneous route. The intradermal route of administration is authorized by the FDA through Emergency Use Authorization since it safely provides a similar immune response against mpox as compared to the two-dose subcutaneous regimen. For individuals under 18 years of age and those with a history of keloid scarring, only subcutaneous administration (0.5 mL per injection) is indicated.	• Alternate Regimen Preparation and Administration Summary – Intradermal Administration (CDC)
Administration Documentation	*Organization must record the following Vaccine Administration these data elements in each vaccine recipient's record. (P.A. #3)* *a. Administration address (including Company)* *b. Recipient name and ID* *c. Recipient date of birth* *d. Recipient sex* *e. Recipient address* *f. Administration date* *g. CVX (product)* *h. Dose number* *i. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])* *j. MVX (manufacturer)* *k. Vaccine administering provider's name and suffix* *l. Administering provider's address, if different than the administration address* *m. Vaccine administration site (on the body)* *n. Vaccine expiration date* *o. Vaccine route of administration*	
	Applies to LHDs and Providers. Same requirement as for COVID-19.	
Reporting Doses Administered	*Organization must submit the following Vaccine Administration Data at least weekly through either (1) the Immunization Information System (IIS) of the state, local, or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation as may be posted on the Provider Agreement update webpage. Data elements marked with an asterisk must also be recorded in the vaccine recipient's medical record:* *a) Administered at location/facility name/ID* *b) Administered at location type*	• Map of CAIR2/RIDE regions • CAIR Mass Vaccination website • My Turn • Enroll in CAIR2

Topic	Requirements & Guidance	Resource Links
	*c) Administration address (including Company)** *d) Recipient name and ID** *e) Recipient date of birth** *f) Recipient sex** *g) Recipient race* *h) Recipient ethnicity* *i) Recipient address** *j) Administration date** *k) CVX (product)** *l) NDC (national drug code)* *m) Dose number** *n) Lot number (Unit of Use [UoU] or Unit of Sale [UoS])** *o) MVX (manufacturer)** *p) Sending organization (name of the entity submitting the report)* *q) Vaccine administering provider's name and suffix** *r) Administering provider's address, if different than the administration address** *s) Vaccine administration site (on the body)** *t) Vaccine expiration date** *u) Vaccine route of administration** *v) Vaccine series*	• Healthy Futures (Technical Support options)
	Important: Report doses administered as soon as possible but at least weekly. CDPH uses this data to calculate and report inventory to CDC. **LHDs and COVID Providers:** Report MPOX doses like you report COVID-19 doses administered. **Non-COVID Providers:** Use (1) My Turn (contact COVID Call Center at 833-502-1245 for assistance), (2) manually enter doses in CAIR (see CAIR2 & RIDE regions), (3) use CAIR Mass Vaccination website, or (4) follow your LHD-approved reporting process. • For new CAIR2 users: Enroll in CAIR to get started if your location has no IIS# • For new RIDE users: See Healthy Futures for technical support options	
VIS & EUA Fact Sheet	Before administering JYNNEOS vaccine, Organization must provide a CDC Vaccine Information Statement (VIS) or FDA Emergency Use Authorization (EUA) Fact Sheet for persons receiving JYNNEOS vaccine under	

Topic	Requirements & Guidance	Resource Links
	EUA, as applicable, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. (P.A. #7) **LHDs and Providers:** Similar requirement as for COVID-19.	• Vaccine Information Statement (VIS) (FDA) • Emergency Use Authorization (EUA) Fact Sheet (FDA)
VAERS Reporting	*Organization must report all SERIOUS ADVERSE EVENTS (AEs) following administration of JYNNEOS vaccine and VACCINE ADMINISTRATION ERRORS to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html. The vaccination provider is responsible for MANDATORY reporting of the following listed events following JYNNEOS vaccination to 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* *Providers are encouraged to also report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event. (P.A. #11)* **LHDs and Providers:** Similar requirement as for COVID-19.	• VAERS website
	Billing & Reimbursement	
Do Not Bill for Vaccine & Kits	*Organization is prohibited from selling or seeking reimbursement for JYNNEOS vaccine doses and any other supplies that the federal government provides without cost to Organization. (P.A. #5)*	

Topic	Requirements & Guidance	Resource Links
	LHDs and Providers: Similar requirement as for COVID-19.	
Billing for Administration Fees	*Organization must administer JYNNEOS vaccine at no cost to the recipient and regardless of the vaccine recipient's ability to pay administration fees. Organization may seek appropriate reimbursement from a program or plan that covers JYNNEOS vaccine administration fees for the vaccine recipient, such as vaccine recipient's private insurance company or Medicare/Medicaid reimbursement. (P.A. #6)*	
	LHDs and Providers: Similar requirement as for COVID-19.	
	Suspension, Termination, Fraud and Abuse	
Suspension & Termination	*Non-compliance with the terms of Agreement may result in suspension or termination from the HHS Mpox Vaccination Program and imposition of criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.*	
	Applies to LHDs and Providers.	
Surrender of Unused Doses	*Upon request by HHS or the relevant public health jurisdiction, Organization must return all JYNNEOS vaccine doses not yet used. (P.A. #14)*	
	Applies to LHDs and Providers.	