Weekly Wrap Up

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Mpox Vaccine Ordering and Commercialization Update

Beginning April 1, 2024, the mpox vaccine JYNNEOS became available on the commercial market. In light of this change, **CDPH strongly encourages LHDs** and **Providers to estimate how much vaccine they will need to continue to** provide vaccine through the summer and the upcoming PRIDE season. Please order estimated doses by Thursday, April 25, 2024.

While there will be opportunities to order from the Federal supply after Tuesday, April 30, 2024, justification for the need for the Federal supply will be required (e.g., lack of access to the commercial vaccine product). Federal ordering will end completely by Tuesday, August 30, 2024.

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PEMGARDA (pemivibart) Emergency Use Authorization (EUA)

PEMGARDA (pemivibart) is a monoclonal antibody that has not been approved but has <u>been authorized for emergency use by the Food and Drug Administration</u>

(FDA) as a pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg) who:

- are not currently infected with SARS-CoV-2 and who have not been known to be exposed to someone who is infected with SARS-CoV-2 and
- have moderate-to-severe immune compromise because of a medical condition or because they receive medicines or treatments that suppress the immune system and they are unlikely to have an adequate response to COVID-19 vaccination.

There is no mention of this product being provided by Federal or State government. For more information please contact the INVIVYD Medical Information Department at 1-800-890-3385 or email medinfo@invivyd.com.

To view all updates, please visit <u>CDC's Interim Clinical Considerations for Use of</u> <u>COVID-19 Vaccines in the United States</u>.

Refer to the FDA Frequently Asked Questions on the Emergency Use Authorization for Pemgarda (pemivibart) for Pre-exposure Prophylaxis (PrEP) of COVID-19, the Fact Sheet: Emergency Use Authorization of PEMGARDA (pemivibart), and the EUA 122 Invivyd PEMGARDA LOA (03222024).

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Reporting and Returning Spoiled/Expired Vaccines

Returning Vaccines by Program

Via the myCAvax system, only spoiled and expired **Bridge Access Program** (BAP) COVID-19, State General Funded (SGF) Flu, Vaccines for Adults (VFA), and LHD 317 vaccines are eligible for vaccine returns and must be reported as waste in myCAvax. (For BAP doses, refer to <u>Reporting & Handling of Nonviable</u> <u>Doses</u> for details.)

Outbreak mpox (JYNNEOS) vaccines are not eligible for returns and should instead be disposed of as medical waste according to practice protocols after the waste has been reported in myCAvax (See <u>Mpox Requirements at a Glance</u> for more details).

Vaccines for Children (VFC) wasted vaccines must be reported in the VFC system. For assistance with VFC returns, providers must contact the VFC help desk via email at <u>myvfcvaccines@cdph.ca.gov</u> or phone at (877)243-8832.

Privately purchased vaccine returns need to be escalated to the manufacturer. Please see EZIZ's <u>Vaccine Ordering and Manufacturer Info</u> page for more details.

For assistance with reporting waste in myCAvax or checking on Return Shipping Label progress, please contact the Provider Call Center at <u>ProviderCallCenter@cdph.ca.gov</u> or 833-502-1245.

Provider Guidance on Returns through myCAvax:

- Return Waste Event Processing Dates:
 - SGF Flu returns will be processed weekly on Tuesdays and Fridays
 - BAP COVID-19 returns will be processed weekly on Wednesdays
 - VFA /LHD 317 returns will be processed on a daily basis, Monday through Friday

• Receiving Return Shipping Labels:

- If 'Email' is selected -the Return Shipping Labels will be sent to the <u>Primary Vaccine Coordinator only</u>, within one business day following CDPH's process of reports into CDC's VTrckS system. All McKesson return label communications will come from the following e-mail address: UPS Quantum View [mail to: <u>pkginfo@ups.com</u>].
- If 'Mail' is selected The postal labels are mailed from the Olive Branch, MS Distribution Center and should arrive within 3-5 business days barring any unforeseen circumstances.

• Returning Vaccine:

- Once a provider receives their return shipping label, they will have 30 days to return the vaccine to McKesson before the label expires.
- <u>Getting Shipment to UPS</u>: If a provider schedules a pick-up of the vaccine shipment from UPS, UPS will send them a pick-up fee. To avoid any fees, the providers should follow the guidance of taking the shipment(s) to an applicable UPS location or giving it to the UPS driver with other outbound shipments (additional details in the Return Shipping Label).

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CDPH Testing Program Updates

CDPH will continue to provide COVID-19 tests to populations at high risk for severe disease through June 30, 2024*. Skilled Nursing Facilities, Elder Care Facilities, Long-Term Care Facilities, Programs serving those >65 years, and Community

Based Organizations that serve the elderly can request at-home tests until **June 30, 2024,** or until testing resources are exhausted.

The FDA extended expiration date on many of these tests will vary, with some tests being shipped out expiring between November 2024 and March 2025. Orders should reflect a 2 - 3 month need of tests.

Use this order form for OTC tests.

Professional CLIA-waived tests are available for facilities with their own CLIAwaver and state facility license through June 30, 2024. Use this <u>order form</u> for professional CLIA-waved tests.

*At-home tests will likely be available for the 2024-2025 respiratory viral season pending the continued availability of tests from the federal government. More information will be forthcoming.

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Vaccines for Children (VFC) Training Feedback Requested

When are you available to attend VFC myCAvax system trainings? CDPH wants to hear from you! Upcoming VFC trainings will be delivered in 30-minute webinars, where providers will learn how to participate in the VFC program using myCAvax.

Please use <u>this survey</u> and select the time windows that generally work best for you to attend trainings. **Responses due by April 19, 2024, at 11:45 PM PT**. CDPH appreciates your feedback!

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VFA Ordering Updates Office Hours

Are you a VFA provider who needs additional support with ordering through the new myCAvax system? Join CDPH for a 30-minute VFA office hours session to learn the latest ordering updates. There will be an opportunity for QA with CDPH subject matter experts.

Register here for the Tuesday, April 23, 2024, 2:00pm – 2:30pm (PT) session.

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Other Upcoming Webinars and Training

Virtual Grand Rounds: Black Health in California - Moving Towards Equity

• <u>Registration link</u> for Tuesday, April 16, 2024, 12:00pm – 1:00pm (PT)

CDPH Immunization Updates for Providers Webinar (occurs every other Friday)

• Register for the next session: Friday April 19, 2024, 9:00am – 10:30am (PT)

June 2024 California Immunization Coalition Summit

• Registration link for June 5-6, 2024, in Sacramento, CA

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Support Opportunities

Provider Call Center

For Program information: email <u>providercallcenter@cdph.ca.gov</u> or call (833) 502-1245 (Monday - Friday, 8:00am - 5:00pm, PT)

myCAvax Help Desk

For technical issues (e.g., password resets): email <u>myCAvax.HD@cdph.ca.gov</u> or call (833) 502-1245, (Monday – Friday, 8:00am – 5:00pm, PT)

System related training materials are available via the Knowledge Center in myCAvax and at <u>EZIZ.org</u>.

My Turn Help Desk

- Onboarding: email <u>myturnonboarding@cdph.ca.gov</u>
- Technical support for My Turn Clinic: email <u>MyTurn.Clinic.HD@cdph.ca.gov</u> or call (833) 502-1245, (Monday – Friday 8:00am – 5:00pm, PT)
- Job aids, demos and training opportunities

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