Friday, April 5, 2024

Weekly Wrap Up

In this message:

JYNNEOS Commercialization

Beginning April 1, 2024, Bavarian Nordic, the maker of JYNNEOS, opened ordering of the vaccine through commercial wholesalers.

At this time, there are no changes to the current ordering process. State, tribal, local, and territory health departments can continue to access the Administration for Strategic Preparedness and Response (ASPR) Strategic National Stockpile supply of JYNNEOS as the commercial availability ramps up. Continue to use your available inventory of JYNNEOS vaccine and continue to order vaccine as usual through myCAvax.

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PEMGARDA (pemivibart) Emergency Use Authorization (EUA)

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

(FDA) under an EUA for the 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 CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States.

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 Reporting & Handling of Nonviable Doses 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 Mpox Requirements at a Glance 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 myvfcvaccines@cdph.ca.gov or phone at (877)243-8832.

Privately purchased vaccine returns need to be escalated to the manufacturer. Please see EZIZ's Vaccine Ordering and Manufacturer Info 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 ProviderCallCenter@cdph.ca.gov 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 Primary Vaccine Coordinator only, 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: pkginfo@ups.com].
  - 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.
  - Getting Shipment to UPS: 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).

The postal labels are mailed from the Olive Branch, MS Distribution Center. They should receive them within 3-5 business days barring any unforeseen circumstances. They send out all printed with the daily mail carrier. Any printed after the carrier has been to the property, go out the next business day.

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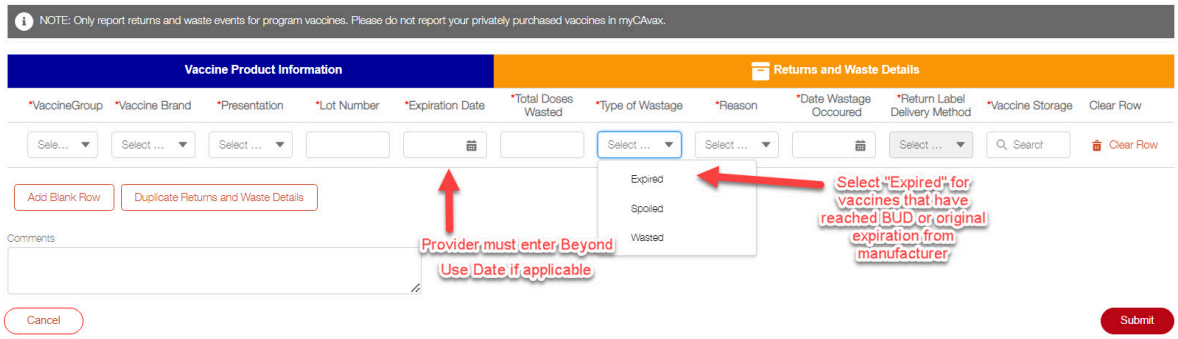
Reporting Beyond Use Date (BUD) vs. Expiration Dates

Expiration dates: The dates determined by the manufacturer beyond which the vaccine is no longer acceptable to administer to patients, regardless of storage condition.

Beyond-Use Dates/Times (BUD): The last day/time that the COVID-19 vaccine can be safely used after it has been transitioned between storage states (thawed, refrigerated, etc.), or altered (diluted, drawn up for administration, etc.) for patient use.

The BUD replaces the manufacturer's expiration date but never extends it. Dispose of the vaccine on whichever date/time comes first!

- Providers reporting waste of vaccines that have reached their beyond use date (BUD), must select "Expired" as the Wastage Type and enter the beyond use date in the "Expiration date" field on the myCAvax waste report as pictured below:



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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 CLIA-waver and state facility license through June 30, 2024. Use this order form 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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End of Respiratory Syncytial Virus (RSV) Season

Administration of nirsevimab is recommended by the CDC from October through March. In alignment with RSV season, CDC has zeroed out our California allocation balances. As a result, the Vaccines for Children (VFC) Program has turned off ordering of the nirsevimab (Beyfortus™) 50mg product. New allocation from CDC for nirsevimab will be implemented for the 2024-2025 season.

Based on current shelf life for nirsevimab, providers with nirsevimab inventory on hand at the end of the 2023-2024 vaccination season should plan to store the product for use in the 2024-2025 season.

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Reminder: End-of-Season Vaccine Dating

COVID-19 vaccine dating is shorter than that of other routine vaccines and will continue to get shorter as we approach the end of the season. COVID-19 doses distributed by McKesson will continue to be distributed until they are 30 days away from the expiry date. This is the same approach used for flu vaccines and helps to reduce vaccine wastage.

For direct ship COVID-19 vaccines, vaccine dating may be similarly shorter compared to earlier in the season. To manage this reduction in shelf life for COVID-19 vaccines toward the end of the vaccination season, CDC recommends that providers order smaller quantities of vaccine and utilize more frequent orders if needed.

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Upcoming Webinars and Training

VFA Office Hours: Ordering in myCAvax

- Registration link for Tuesday, April 9, 2024, 2:00pm – 2:30pm (PT)

Healthy Places Index (HPI) Toolkit Training

- Registration link for Thursday, April 11, 2024, 1:00pm – 2:00pm (PT)

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

- Registration link 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 providercallcenter@cdph.ca.gov or call (833) 502-1245 (Monday - Friday, 8:00am - 5:00pm, PT)

myCAvax Help Desk

For technical issues (e.g., password resets): email myCAvax.HD@cdph.ca.gov 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 EZIZ.org.

My Turn Help Desk

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

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EZIZ.org

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