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COVID-19 Vaccine Information Brief

June 3, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Vaccine Information Brief will be June 17, 2022

IMPORTANT/NEW COVID-19 Vaccine Information

- Pfizer COVID-19 Adult Vaccine Comirnaty[®]
- Clinical Guidance Update: COVID-19 Vaccination
- New Resources to Encourage COVID-19 Vaccination for Children and Teens
- Vaccination Cards and Additional Doses of COVID-19 Vaccine
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

Pfizer COVID-19 Adult Vaccine – Comirnaty[®]

The licensed Pfizer COVID-19 vaccine for adults (the Biologics License Application [BLA] labeled product known as Comirnaty[®]) will soon be available to Iowa healthcare providers.

- It is anticipated Comirnaty[®] will be used to fill a portion of all Pfizer adult vaccine orders beginning the week of June 13, 2022.
 - The EUA labeled product will remain available during and after the use of the BLA-labeled product. Both products will be co-circulating during this limited release with a GRAY Cap for both labels.
- The EUA and BLA products have different labels and NDCs; however, the vaccines are identical and interchangeable, as determined by the FDA. The storage and handling guidelines are the same for both products. See the COVID-19 Vaccine Quick Reference Guide for details.
- The EUA and BLA are identical and interchangeable for both primary and booster vaccinations. Support and education will be provided by Pfizer and the CDC to help stakeholders understand the labeling differences to ensure all vaccines are administered correctly.

Clinical Guidance Update: COVID-19 Vaccination - Updated May 20, 2022

CDC updated <u>COVID-19 vaccination guidance</u> including:

- New guidance for use of a Pfizer-BioNTech COVID-19 Vaccine booster dose in children ages 5–11 years
- Updated guidance that the following people should receive a second COVID-19 booster dose:
 - People ages 12 years and older who are moderately or severely immunocompromised
 - People ages 50 years and older
- Updated guidance for people who are moderately or severely immunocompromised and are treated with B-cell-depleting therapies
- Updated guidance for primary series vaccination after SARS-CoV-2 infection
- Clarification of COVID-19 vaccination guidance for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A)
- <u>Up to date</u>: People ages 5 years and older are up to date with their COVID-19 vaccines when they have received all doses in the primary series and all booster doses recommended for them, when eligible.
 - Vaccine recommendations differ depending on a person's age, immune status, vaccine received for the primary series (mRNA or Janssen), and time since last dose.
 - On May 20, 2022, CDC strengthened its second booster recommendations. People ages 50 years and older and people ages 12 years and older who are moderately or severely immunocompromised should get a second booster dose to be up to date.
 - People ages 18 through 49 years who received a Janssen COVID-19 vaccine for both their primary and booster dose may get a second booster dose of either Pfizer-BioNTech or Moderna COVID-19 vaccine, but the second booster dose is not required to be considered up to date.

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

New Resources to Encourage COVID-19 Vaccination for Children and Teens

As children and teens continue to get vaccinated against COVID-19, CDC is sharing new resources for parents, vaccine providers, and partners. A <u>new website for parents and caregivers</u> includes information on COVID-19 vaccination for children and adolescents. <u>Two new fact sheets</u> are available in nine languages that can be printed and shared. In addition, a list of <u>resources for vaccine providers</u> is available to help support conversations with families about vaccination and to highlight ways to improve vaccine accessibility for children, including those with disabilities and special healthcare needs. Healthcare providers can visit <u>COVID-19 Vaccination for Children</u> for up-to-date information and resources to help inform planning for pediatric vaccination.

For community partners and vaccine providers

- <u>Resources to Promote COVID-19 Vaccination for Children & Teens</u> contains information to help navigate conversations with parents and caregivers. A suite of digital and downloadable resources is available to share with families including content for social media, videos, printable fact sheets, web pages, and more.
- <u>Quick Conversations Guide</u> helps navigate answers to common questions parents and caregivers may have about the COVID-19 vaccine for children. Providers can use this guide to address concerns and help parents feel more confident about vaccinating their children.

- <u>Vaccinating Children with Disabilities Against COVID-19</u> includes strategies to improve COVID-19 vaccine accessibility for children with disabilities and special healthcare needs.
- <u>COVID-19 Vaccination for Children</u> serves as a landing page for jurisdictions, community partners, and vaccine providers to find up-to-date information and resources to help inform vaccination planning for children and teens who are eligible.
- <u>Equity in Childhood COVID-19 Vaccination</u> webpage highlights the work currently being done and resources to improve vaccine access and equity.

For parents and caregivers

- The new <u>COVID-19 Vaccines for Children and Teens</u> site is structured to help parents and caregivers easily find information on various topics, including:
 - why children and teens should get vaccinated
 - vaccine safety
 - <u>side effects</u>
 - preparing for vaccination and more.
- <u>Two new facts sheets</u> are available in nine languages that can be printed and shared

Vaccination Cards and Additional Doses of COVID-19 Vaccine

If there is no space on a vaccine card to document additional or repeated doses of COVID-19 vaccine, please document new vaccinations on a NEW card and staple all patient vaccine cards together. This will ensure the patient has all of their vaccine records maintained in a single location.

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

At this time, the Medical Affairs team is continuing to educate providers on Purple, Gray, and Orange caps as well as medical updates. To access dates and links for upcoming training sessions, please visit: https://www.pfizermedicalinformation.com/en-us/medical-updates.

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958. Healthcare providers may also visit the CDC's Vaccine Lot Number and Expiration Date web page and complete the registration form to request access to COVID-19 vaccine expiration dates.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a <u>placeholder date</u>. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. It is important for healthcare providers to update vaccine expiration dates in IRIS.

The Pfizer COVID-19 vaccine:

It is important for all healthcare providers to double check all shelf life extensions for all Pfizer products. Pfizer does not have an expiration date look up tool for these vaccines. The date on the label is <u>NOT</u> the expiration date for the GRAY and ORANGE cap vials, instead, each vial has the lot number and date of manufacture printed on the label. Pfizer does provide guidance for expiration dates on their <u>website</u>.

- *Regardless of storage condition, <u>GRAY CAP</u> and <u>ORANGE CAP</u> vaccine vials should not be used after 12months from the **date of manufacture** printed on the vial and cartons.
- †The <u>PURPLE CAP</u> vaccine vials should not be used past the 12-month expiry. For vials with expiry dates of October 2021 through March 2022, the printed date on the label/carton reflects 6-month expiry. For vials with expiry dates of June 2022-December 2022, the printed date on the label/carton reflects
 9-month expiry. The vaccine should not be used past the 12-month (updated) expiry date in the table below.

Resources for Pfizer COVID-19 vaccine:

- FDA COVID-19 Vaccine Page (Page will be updated with latest EUA changes)
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (5-11 years of age), DILUTE BEFORE USE, Orange Cap



Expiry information for Ages 5 through 11 DILUTE BEFORE USE Orange Cap presentation* and Ages 12 years and older DO NOT DILUTE Gray Cap presentation*

Printed Manufacturing Date	12-Month Expiry Date
06/2021	31-May-2022
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-0ct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023

Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation [†]		
Printed Expiry Date	Updated Expiry Date	
10/2021	30-Apr-2022	
11/2021	31-May-2022	
12/2021	30-Jun-2022	
01/2022	31-Jul-2022	
02/2022	31-Aug-2022	
03/2022	30-Sept-2022	
07/2022	31-0ct-2022	
08/2022	30-Nov-2022	
09/2022	31-Dec-2022	
10/2022	31-Jan-2023	
11/2022	28-Feb-2023	

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to <u>www.vaxcheck.jnj/</u>

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to <u>www.modernatx.com/covid19vaccine-eua/</u>

CDC's <u>COVID-19 Vaccine Expiration Date Tracking Tool</u> can help providers keep track of the expiration date by lot number.

V-safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: posted on the vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- <u>V-safe Print Resources</u>
- V-safe Poster-11x17
- Vaccine Adverse Event Reporting System (VAERS)