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California Department of Public Health

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TO: California Providers of Pediatric Services

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SUBJECT: Updated Pfizer-BioNTech COVID-19 Vaccines, mRNA primary series for children 6 months through 17 years.

HIGHLIGHTS

- Pfizer-BioNTech COVID-19 Vaccine is currently recommended beginning at age 6 months, with the number and volume of doses varying by age (CDPH COVID-19 Vaccine Timing):
  - For children 6 months through 4 years of age, as a three-dose series, with doses 1 and 2 given 3-8 weeks apart, and doses 2 and 3 given at least 8 weeks apart.
  - For children 5 through 17 years of age, as a two-dose series given 3-8 weeks apart; an additional dose at least 4 weeks following the second dose is recommended for certain kinds of immunocompromise.

- The formulations for children and adolescents are supplied in multiple dose vials with different colored caps and label borders, depending on age (CDPH COVID-19 Vaccine Product Guide). Formulations for different age groups should not be used interchangeably.

- Under initial standards, unopened vials may be stored in a vaccine refrigerator at 2ºC to 8ºC for up to 10 weeks or in an ultra-low temperature freezer at -90°C to -60°C until the published expiration date. (Do not store vials in a routine, standard temperature vaccine freezer.) Vials should be discarded 12 hours after puncture.

- The information sheet about the v-safe smartphone safety monitoring system should be provided to parent/guardians, who should be encouraged to participate.

- This letter is intended to provide information common to all formulations of pediatric Pfizer-BioNTech COVID-19 vaccine, as well as point out age-specific differences, and links to CDC, CDPH, FDA and other resources.

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SUMMARY

In June 2022, the Centers for Disease Control and Prevention (CDC) expanded its recommendation for use of the Pfizer-BioNTech COVID-19 Vaccine, under federal Food and Drug Administration Emergency Use Authorization (EUA), to children 6 months through 17 years of age who do not have specific rare contraindications.

BACKGROUND AND COMPOSITION

The Pfizer-BioNTech COVID-19 Vaccine is currently licensed under Biologics License Application (BLA) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 6 months through 11 years of age. A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine is authorized for administration at least 4 weeks following the second dose to individuals 5 years and older who have been determined to have certain kinds of immunocompromise.

Vaccine components include those listed below, with quantities differing by vaccine formulation:

- Lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC])
- Sucrose
- Diluent (sterile 0.9% Sodium Chloride Injection, USP)

The 6 months through 11 years formulation also includes:

- Tromethamine and tromethamine hydrochloride

The 12 years and older formulation also includes:

- Potassium chloride
- Monobasic potassium phosphate
- Dibasic sodium phosphate dihydrate

The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative. The vial stoppers are not made with natural rubber latex.

More information, including composition, can be found in age-appropriate letters at the following site Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA.

ACIP RECOMMENDATIONS FOR VACCINE USE

Eligible Groups

Pfizer-BioNTech COVID-19 Vaccine may currently be given to any individual 6 months through 11 years under the EUA. The FDA has fully approved the Pfizer-BioNTech COVID-19, marketed as Comirnaty, for the prevention of COVID-19 in individuals 12

years of age and older. Current COVID-19 vaccine recommendations by ACIP and CDC may be found at COVID-19 ACIP Vaccine Recommendations. Individuals 5 years and older who are moderately or severely immunocompromised are eligible for an additional dose to complete the primary series. ACIP recommends that individuals 5 years and older receive a bivalent booster dose, at least 2 months after completion of their primary series. Further information can be found in the Bivalent Booster Provider Letter.

Minimum Ages and Intervals

- Minimum age for any dose: 6 months
- Minimum interval between dose 1 and 2: 21 days
- Minimum interval between dose 2 and 3 (for children 6 months through 4 years of age): 8 weeks
- Minimum interval between primary series and additional dose (only for individuals 5 years and older who have moderate or severe immune compromise): 28 days

Contraindications and Precautions

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or a known diagnosed allergy to a component of the Pfizer-BioNTech COVID-19 Vaccine, as listed on the FDA fact sheets.

CDC considers a history of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”]) to be a precaution but not a contraindication to vaccination. Additional clinical considerations and information on contraindications and precautions can be found in the CDC Use of COVID-19 Vaccines in the United States Interim Clinical Considerations.

Administration with Other Vaccines

COVID-19 vaccines may be administered without regard to timing of other vaccines, including on the same day as other vaccines. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. Muscles that may be used for multiple injections include:

- Ages ≥3 years: Deltoid
- Ages 6 months–2 years: Vastus lateralis of the anterolateral thigh

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs, if possible.

See general best practices and The Epidemiology and Prevention of Vaccine-Preventable Diseases: “the Pink Book” for further information.

DOSAGE AND ADMINISTRATION

Dosage varies by age (see also the CDPH COVID-19 Vaccine Product Guide):

- 6 months through 4 years 3 micrograms/dose
- 5 years through 11 years 10 micrograms/dose
- 12 years and older 30 micrograms/dose

For reference, please see the CDPH COVID-19 Vaccine Timing job aid. Interim schedules can also be found in table 2 of the Interim Recommendations of the Advisory Committee on Immunization Practices.

Storage and Handling

Storage and handling are the same for all tris-sucrose (maroon, orange, and gray cap formulations of Pfizer-BioNTech COVID-19 Vaccine. (For purple cap, see here.)

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze thawed vials. Thawed vials can be handled in room light conditions.

Current Storage Standards for all tris-sucrose Pfizer Cap Formulations	Viability
ULT Freezer (-90°C to -60°C)	Until expiration
Refrigerator (2°C to 8°C)	Up to 10 weeks
After puncture	12 hours
Standard freezer (-25°C to -15°C)	**Do not store**
Thermal shipper	**Do not store**

Vial Storage

Frozen Storage: If cartons were initially received frozen at ultracold conditions in thermal containers with dry ice, then cartons can be stored at ultracold temperatures between -90°C and -60°C (-130°F to -76°F) until the published expiration date. If cartons were received at refrigerated temperature and not at ultracold conditions, then they should be placed directly into the refrigerator.

Storage after Thawing: **Do not refreeze once thawed**.

- Storage at 2°C to 8°C (36°F to 46°F): Vials can be stored in the refrigerator at 2°C to 8°C for up to 10 weeks. After 10 weeks in the refrigerator, the vials must be discarded.
- Room temperature storage and storage after dilution: Vials may be stored between 8°C to 25°C for up to 12 hours prior to dilution. After dilution, the vial should be held between 2ºC to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution, even though some vial and carton labels may state that a vial should be discarded 6 hours after dilution.

Regardless of storage condition, the vaccine should not be used after expiry. Expiry dates for Pfizer vaccines are published in the EUA, and the EUA is updated when shelf-life extensions are authorized.

Transportation of Vials

If local redistribution is needed, undiluted vials previously stored in an ultracold freezer may be transported at -90°C to -60°C (-130°F to -76°F) or at 2°C to 8°C (35°F to 46°F). Undiluted vials previously stored in a refrigerator should be transported at 2°C to 8°C (35°F to 46°F).

REACTOGENICITY AND ADVERSE EVENTS

Available safety and immunogenicity data for Pfizer-BioNTech COVID-19 Vaccines in children and adolescents are similar to those seen in young adults. Materials presented at ACIP meetings regarding safety and immunogenicity data can be found at the COVID-19 ACIP Vaccine Recommendations.

Adverse reactions noted during clinical trials varied by age group:

6 months through 23 months of age: irritability, decreased appetite, tenderness at the injection site, injection site redness, fever, injection site swelling, and lymphadenopathy.

24 months through 4 years of age: pain at the injection site, fatigue, injection site redness, fever, headache, injection site swelling, chills, muscle pain, joint pain, and lymphadenopathy.

5 years through 17 years of age: pain at the injection site, fatigue, injection site redness, fever, headache, injection site swelling, chills, muscle pain, joint pain, lymphadenopathy, nausea, rash, malaise, decreased appetite, diarrhea, vomiting, and pain in extremity.

Before vaccination, providers should counsel COVID-19 vaccine recipients, parents, or guardians about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination reactions. Localized axillary lymphadenopathy on the same side as the vaccinated arm has been observed following vaccination with mRNA COVID-19 vaccines.

Antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms; these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms. In general, aspirin is not recommended for use in children and adolescents ages 17 years and younger as an antipyretic or analgesic due to the risk of Reye's syndrome.

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines before COVID-19 vaccination to prevent allergic reactions is not generally recommended. CDC recommends that providers consider observing all vaccine recipients for 15 minutes after vaccination for syncope.

Additionally, providers should consider observing people with the following medical histories for 30 minutes to monitor for allergic reactions:

- An allergy-related contraindication to a different type of COVID-19 vaccine.
- Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
- Anaphylaxis after non-COVID-19 vaccines or injectable therapies.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs. Further information on anaphylaxis management can be found in the interim considerations for the Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination and laboratory evaluation of people who experience anaphylaxis after vaccination.

Syncope (fainting) may occur in association with any injectable vaccine, especially in adolescents. Procedures should be in place to prevent falling injuries and manage syncopal reactions. People should be seated or lying down during vaccination and observed for 15 minutes after vaccination as noted above. If syncope develops, patients should be observed until symptoms resolve.

Myocarditis is a rare, serious adverse event that has been reported primarily after receipt of the second dose of mRNA COVID-19 vaccines, with the highest risk currently observed in males aged 12–39 years. The rare risk of myocarditis might be further reduced by a longer interval between the first and second dose. FDA has authorized and ACIP and CDC have recommended Pfizer-BioNTech COVID-19 vaccines in children aged 6 months through 17 years based on the determination that the benefits of COVID-19 vaccination outweigh the risks.

Further information on Reactogenicity and Adverse Events can be found at the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States website under the headings:

- Patient Counseling
- Contraindications and Precautions
- Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech & Moderna.

VACCINE INFORMATION FACTSHEET

Prior to a child younger than 18 years receiving Pfizer-BioNTech COVID-19 Vaccine, share with the parent or guardian:

- Information consistent with the age-appropriate "Vaccine Information Fact Sheet for Recipients and Caregivers", and
- A copy of the age-appropriate Vaccine Information Fact Sheet, or direct the parent or guardian to www.cvdvaccine.com.

Documentation for Children 6 months through 17 years

Provide a vaccination card to the parent/guardian that includes the date when the recipient needs to return for the next dose. Administration of each dose must be reported to the state or regional immunization registry.

To help monitor immunization safety in children, provide the v-safe information sheet to parent/guardians and encourage them to participate in v-safe. For more information, visit: www.cdc.gov/vsafe.

Reporting of vaccine adverse events
Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death.

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

Additional CDC guidance on preventing, reporting, and managing administration errors can be found at Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.

ORDERING AND BILLING

Order Pfizer-BioNTech COVID-19 Vaccine via your provider myCAvax account.

Billing Information for Vaccine
COVID-19 vaccines have been purchased by the federal Government for all people in the US, regardless of insurance or immigration status, at no cost to recipients.

Vaccination providers are only able to be reimbursed for administering the vaccine. They may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient. However, there should be no patient cost sharing, or out-of-pocket cost, for all payor types for vaccine administration regardless of whether or not the vaccinator is in the payor's provider network. Providers may not charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided, nor require additional medical services to receive COVID-19 vaccination. California Medical Association has provided a guide on reimbursement.

Medi-Cal Fee-For-Service and Medi-Cal Managed Care
The Department of Health Care Services is reimbursing the COVID-19 vaccine administration reimbursement under its fee-for-service (FFS) system. To avoid delays and denials in payment, physicians will need to submit claims for COVID-19 vaccine administration to Medi-Cal FFS rather than Medi-Cal managed care plans.

- CLAIM SUBMISSION – Medi-Cal FFS and Medi-Cal managed care claims should be submitted directly to Medi-Cal FFS with the patient's Medi-Cal FFS Benefit Identification Card (BIC) ID number rather than the managed care plan ID number.

- BILLING – Because vaccine has been purchased by the federal government, claims should include vaccine administration CPT codes only (not vaccine cost codes).
- REIMBURSEMENT RATE (ADMINISTRATION) – $40 for each dose approved.

RESOURCES

- FDA EUA Fact Sheets for either Healthcare Providers or Recipients and Caregivers
- EZIZ COVID-19 Resources on vaccine management, administration, and more.
- CDC Administration Overview of Pfizer-BioNTech COVID-19 Vaccines: job aids.
- CDC Use of COVID-19 Vaccines in the US: Interim Clinical Considerations
- AAP members may access vaccine resources at www.cispimmunize.org/.
- Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.
- Vaccine Injury Compensation Program (VICP) includes Pfizer-BioNTech COVID-19 Vaccine
- Additional information on vaccines can be found at http:/www.cdc.gov/vaccines/.
- Provider Letter with information on Bivalent Boosters.