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California Department of Public Health

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TO: California Providers of Pediatric Services

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SUBJECT: Pfizer-BioNTech COVID-19 Vaccine, mRNA for children 6 months through 4 years: Preliminary information

HIGHLIGHTS

- Pfizer-BioNTech COVID-19 Vaccine is now recommended for children 6 months through 4 years of age as a three-dose primary series, at a dose of 3 micrograms (0.2 mL). Dose 1 and 2 are separated by 3 to 8 weeks; dose 2 and 3 are separated by at least 8 weeks.
- The vaccine for this age group is supplied in a new multiple dose vial with a maroon cap, a label with a maroon border, **and a diluent** that results in a different concentration than the formulation for persons 5 years or older. Formulations for older persons should not be used in this age group.
- 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. (Until any updates to these standards, do not store vials in a routine, standard temperature vaccine freezer.)
- The information sheet about the *V-safe* smartphone safety monitoring system should be provided to parent/guardians, who should be encouraged to participate.
- The information in this letter applies to the Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a **maroon** cap and a label with a maroon border and which **MUST BE DILUTED** before use. The initial vials/cartons may be mislabeled, but the vaccines are authorized for use in 6 months through 4 years. A letter explaining the mislabeling will be included with shipments.

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SUMMARY

On June 18, 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 4 years of age who do not have specific rare contraindications.

BACKGROUND AND COMPOSITION

The Pfizer-BioNTech COVID-19 Vaccine is currently licensed to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 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 15 years of age.

For children 6 months through 4 years of age, the vaccine is administered as a three-dose primary series at a dose of 3 micrograms (less than the 10 microgram dose used for persons 5-11 years and older). Dose 1 and 2 are separated by 3 to 8 weeks; dose 2 and 3 are separated by at least 8 weeks.

Each 0.2 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with maroon caps and labels with maroon borders also includes the following ingredients: lipids (0.04 mg ((4- hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide, 0.01 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.02 mg cholesterol), 3.2 mg sucrose, 0.006 mg tromethamine, and 0.04 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.52 mg sodium chloride per dose.

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

ACIP RECOMMENDATIONS FOR VACCINE USE

Eligible Groups

Pfizer-BioNTech COVID-19 Vaccine may currently be given to any individual 6 months through 4 years under the EUA. Children ages 5 years and over are eligible for a single booster dose at least 5 months after the final dose in the primary series.

Individuals 6 months through 4 years who are moderately or severely immunocompromised are not eligible for an additional dose at this time. Individuals 5 years and older who are moderately or severely immunocompromised are eligible for an additional dose to complete the primary series and become eligible for a booster dose 3 months after the final dose in the primary series.

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 individuals 6 months through 4 years): 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 history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine. Vaccine components are listed in the FDA fact sheet.

CDC considers a history of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., 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 information on contraindications and precautions can be found inthe CDC Clinical Considerations for Use of COVID-19 vaccines section on Contraindications and Precautions.

Administration with Other Vaccines

COVID-19 vaccines may be administered without regard to timing of othervaccines, 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 Pink Book for further information.

Additional Clinical Considerations

Please refer to the CDC Clinical Considerations for Use of COVID-19 vaccines.

VACCINE INFORMATION FACTSHEET

Prior to a child 6 months through 4 years of age receiving Pfizer-BioNTech COVID-19 Vaccine, providers must:

- Communicate to the parent or guardian information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" and
- Provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet.

Documentation for Children 6 months through 4 years

Provide a vaccination card to the parent/guardian that includes the date when the recipient needs to return for the second 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, which also reminds parents about second doses. For more information, visit: www.cdc.gov/vsafe.

DOSAGE AND ADMINISTRATION

The information in this letter applies to the Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a **maroon** cap and a label with a maroon border and which **MUST BE DILUTED** before use**.** As some initial vials/cartons may be mislabeled, regardless of the ages listed on the packaging the vaccines are authorized by FDA for use in 6 months through 4 years. A letter explaining the mislabeling will be included with shipments. For additional information, please refer to the CDPH COVID-19 vaccine Product Guide.

Pfizer-BioNTech Pediatric (6 months through 4 years)

Packaging	
Vial cap color	Maroon
Doses per vial	10 doses
Carton Size	100 doses
Carton NDC #	59267-0078-4
Administration	
Dose	3 micrograms
Dilution Information	Dilute with 2.2 mL sterile 0.9% Na CL Injection, USP
Injection volume	0.2 mL

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze thawed vials.

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

Vial Storage Prior to Use

Appropriate storage of cartons of Pfizer-BioNTech COVID-19 Vaccine multiple- dose vials with maroon caps depends on the temperature at which the vaccine is received.

- If cartons are received frozen at ultra-cold conditions in thermal containers with dry ice, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 4 hours to thaw at this temperature. Alternatively, frozen vials may be stored in an ultra-low temperature (ULT) freezer at -90ºC to -60ºC (-130ºF to -76ºF) until the published expiration date. **Do not store vials at -25°C to -15°C (-13°F to 5°F)**. Once vials are thawed, they should not be refrozen.
- If cartons are received at refrigerator temperatures (2°C to 8°C), they should be stored in the refrigerator at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

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. Below are the expiry dates of the vaccine at the time the initial EUA was published:

Printed Manufacturing Date	12-Month Expiry Date
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023
04/2022	31-Mar-2023
05/2022	30-Apr-2023
06/2022	31-May-2023

Vial Storage During Use

If not previously thawed in refrigerator at 2ºC to 8ºC (35ºF to 46ºF), allow vials to thaw at room temperature [up to 25ºC (77ºF)] for 30 minutes.

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with maroon caps and labels with maroon borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution and 12 hours after puncture.

Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the full EUA Prescribing Information, currently 12 hours after puncture, supersedes the number of hours printed on vial labels and cartons.

Transportation of Vials

If local redistribution is needed, undiluted vials 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).

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. Adverse reactions in participants 6 through 23 months of age following administration of the Pfizer-BioNTech COVID-19 Vaccine included irritability, decreased appetite, tenderness at the injection site, injection site redness, fever, injection site swelling, and lymphadenopathy. Adverse reactions in participants 2 through 4 years of age following administration of the Pfizer-BioNTech COVID-19 Vaccine included pain at the injection site, fatigue, injection site redness, fever, headache, injection site swelling, chills, muscle pain, joint pain, and lymphadenopathy.

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 observation of all vaccine recipients for at least 15 minutesafter vaccination, and up to 30 minutes for persons at higher risk of anaphylaxis. 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 forthe 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. FDA has authorized and ACIP and CDC have recommended Pfizer-BioNTech vaccines in children aged 6 months through 4 years, and older children and adolescents aged 5 through 17 years based on the determination that the benefits of COVID-19 vaccination outweigh risks in these populations.

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 and Moderna

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 here.

ORDERING AND BILLING

myCAvax Ordering

Providers may order Pfizer-BioNTech COVID-19 Vaccine via their myCAvax account.

Billing Information for Vaccine

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

Since the federal government has purchased the vaccine, 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.

The California Medical Association has provided a helpful 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) delivery system. To avoid delays and denials in payment, physicians will need to ensure claims for COVID-19 vaccine administration are submitted to Medi-Cal FFS rather than Medi-Cal managed care plans.

- CLAIM SUBMISSION - Medi-Cal FFS and Medi-Cal managed care claims should besubmitted 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 the federal government is supplying the vaccine itself at no cost, physicians should not bill for the vaccine itself. Claims should include the vaccine administration CPT codes only.
- REIMBURSEMENT RATE (ADMINISTRATION) – $40 for each dose approved.

RESOURCES

Vaccine Information Factsheet: The latest Vaccine Information Factsheet can be found on the FDA webpage.

EZIZ COVID-19 Resources: Updated information on vaccine management, administration, and more.

CDC Administration Overview of Pfizer-BioNTech COVID-19 Vaccine: Includes job aids for vaccine preparation, storage and handling, transport guidance, and more.

FDA Emergency Use Authorization Fact Sheet for Pfizer-BioNTech COVID-19 Vaccine for 6 months through 4 years of age

CDC Interim Clinical Considerations for Use of COVID-19 vaccines Currently Approved or Authorized in the United States

AAP vaccine recommendations and other information about COVID-19 vaccines are available to AAP members at http://www.cispimmunize.org/.

Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.

Vaccine Injury Compensation Program (VICP): Pfizer-BioNTech COVID-19 Vaccine™ is covered by the federal VICP.

Additional information on vaccines can be found at http://www.cdc.gov/vaccines/.