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TO: California Providers of Pediatric Services

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SUBJECT: Pfizer-BioNTech COVID-19 Vaccine, mRNA for children 5-11 years:
Preliminary information

HIGHLIGHTS

- Pfizer-BioNTech COVID-19 Vaccine is now recommended for children 5 to 11 years of age as a two-dose primary series, given 3 weeks apart, at a dose of 10 micrograms (0.2 ml).
- The vaccine for this age group is supplied in a new multiple dose vial with an orange cap, a label with an orange border, and a diluent that results in a different concentration than the formulation for persons 12 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 2°C to 8°C for up to 10 weeks or in an ultra-low temperature freezer at -90°C to -60°C for up to 6 months. (Until any updates to these standards, do not store vials in a routine 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.

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SUMMARY

On November 2, 2021, 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 5-11 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. Emergency use authorization is currently granted for use in those 5 to 15 years of age.

For children 5 through 11 years of age, the vaccine is administered as a two-dose primary series, 3 weeks apart, at a dose of 10 micrograms (less than the 30 microgram dose used for persons 12 years and older).

Each 0.2 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with orange caps and labels with orange borders also includes the following ingredients: lipids (0.14 mg (4- hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide, 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 10.3 mg sucrose, 0.02 mg tromethamine, and 0.13 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) has 0.9 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 5 to 11 years of age under the EUA. Individuals 12 and older who are [moderately or severely immunocompromised](#) are eligible for an additional dose after the primary series under EUA. Individuals under 18 are not eligible for booster vaccinations at this time.

Minimum Ages and Intervals

- Minimum age for any dose: 5 years
- Minimum interval between dose 1 and 2: 21 days
- Minimum interval between primary series and additional dose (only for individuals 12 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. Vaccine components are listed on the [CDC website](#).

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 in the [CDC Clinical Considerations for Use of COVID-19 vaccines](#).

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 ≥11 years: Deltoid

Ages 5–10 years: Vastus lateralis of the anterolateral thigh is preferred.

[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 if possible in different limbs COVID-19 vaccine and vaccines that may be more likely to cause a local reaction.**

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 5 to 11 years old 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 5-11 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 an orange cap and a label with an orange border and which **MUST BE DILUTED** before use. The carton labels state: For age 5 years to <12 years. For additional information, please refer to the [CDPH COVID-19 vaccine Product Guide](#).

Packaging	
Vial cap color	Orange
Doses per vial	10 doses
Carton Size	100 doses
Carton NDC #	59267-1055-4
Administration	
Dose	10 micrograms
Dilution Information	Dilute with 1.3 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 Orange Cap Formulation*	
ULT Freezer (-90°C to -60°C)	Up to 6 months
Refrigerator (2°C to 8°C)	Up to 10 weeks
Standard freezer (-25°C to -15°C)	Do not store until further notice

Vial Storage Prior to Use

Appropriate storage of cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange 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 [2°C to 8°C (35°F to 46°F)], 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. Alternately, frozen vials may be stored in an ultra-low temperature (ULT) freezer at -90°C to -60°C (-130°F to -76°F). **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 standard freezer temperatures (-25°C to -15°C (-13°F to 5°F)), frozen vials should be immediately transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], 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. **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, and may be stored for up to 10 weeks. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

The date printed on the orange capped vials is the date of manufacture, **NOT** the date of expiration. The expiration date is 6 months from the date of manufacture, including the month of manufacture. Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.

Vial Storage During Use

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

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

After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Record the date and time of first vial puncture on the vial label. Vials should be discarded 12 hours after dilution. The information in the FDA EUA Fact Sheet supersedes the number of hours printed on vial labels and cartons. (Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture.)

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. [Local and systemic reactions](#) following vaccination are less frequent in children aged 5–11 years compared with [young adults aged 16–25 years](#). 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 in the same arm injected with mRNA COVID-19 vaccine has been observed. Routine prophylactic administration of antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) to prevent post-vaccination symptoms is **not recommended**.

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. CDC recommends observation of all vaccine recipients for at least 15 minutes after 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 for the [management of anaphylaxis following 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 after receipt of the second dose of mRNA COVID-19 vaccines, with the highest risk currently observed in males aged 12–29 years. FDA has authorized and ACIP and CDC have recommended Pfizer-BioNTech vaccines in children aged [5–11 years](#) and adolescents aged [12–17 years](#) based on the determination that the benefits of COVID-19 vaccination outweigh risks in these populations. More information can be found [here](#).

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 clear 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 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

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 Product Insert for Pfizer-BioNTech COVID-19 Vaccine](#)

[CDC 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 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/>.