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TO: California Providers of Pediatric Services

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SUBJECT: Moderna COVID-19 Vaccine, mRNA for children 6 months through 5 years: Preliminary information

HIGHLIGHTS

- Moderna COVID-19 Vaccine is now recommended for children 6 months through 5 years of age as a two-dose primary series at a dose of 25 micrograms (0.25 mL), given 4 to 8 weeks apart. The vaccine is also authorized for administration at least 1 month following the second dose to individuals 6 months through 5 years of age with certain kinds of immunocompromise.
- The vaccine for the 6 months through 5 years age group is supplied in a new multiple dose vial with a blue cap, a label with a magenta border, and does not require diluent. Formulations for older persons should not be used in the younger age groups.
- Under initial standards, unopened vials may be stored frozen between -50°C to -15°C (-58°F to 5°F) until the published expiration date or for up to 30 days at 2°C to 8°C (36°F to 46°F) prior to first use.
- The information sheet about the *V-safe* smartphone safety monitoring system should be provided to parent/guardians, who should be encouraged to participate.
- Information regarding the Moderna COVID-19 Vaccine for children 6 years through 17 years of age will be shared in a future letter.

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SUMMARY

On June 18, 2022, the Centers for Disease Control and Prevention (CDC) expanded its recommendation for use of the Moderna COVID-19 Vaccine, under federal Food and Drug Administration Emergency Use Authorization (EUA), to children 6 months through 5 years of age who do not have specific rare contraindications.

BACKGROUND AND COMPOSITION

The Moderna COVID-19 Vaccine is currently licensed to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 3 (SARS-CoV-2) in individuals 18 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, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 6 months of age and older.

The Moderna COVID-19 Vaccine, supplied in a multiple-dose vial with a dark blue cap and a label with a magenta border, is administered as a primary series of two doses (0.25 mL each) 1 month apart to individuals 6 months through 5 years of age.

A third primary series dose (0.25 mL) of the Moderna COVID-19 Vaccine, supplied in a multiple-dose vial with a dark blue cap and a label with a magenta border, is authorized for administration at least 1 month following the second dose to individuals 6 months through 5 years of age who have been determined to have certain kinds of immunocompromise.

Each 0.25 mL primary series dose of Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a magenta border contains 25 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus. Each 0.25 mL dose of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a magenta border contains the following ingredients: a total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.

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

ACIP RECOMMENDATIONS FOR VACCINE USE

Eligible Groups

Moderna COVID-19 Vaccine may currently be given to any individual 6 months through 17 years of age under the EUA. Individuals 6 months and older who are moderately or severely immunocompromised are eligible for an additional dose to complete the primary series. Individuals 18 years and over are eligible for a single booster dose at least 5 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: 28 days
- Minimum interval between primary series and additional dose (only for individuals 6 months and older who have moderate or severe immune compromise): 28 days

Contraindications and Precautions

Do not administer Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine or a known diagnosed allergy to a component of the Moderna COVID-19 Vaccine. Vaccine components are listed on 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 in the 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 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 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 5 years of age receiving Moderna 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 https://eua.modernatx.com/covid19vaccine-eua/recipients/ to obtain the Vaccine Information Fact Sheet.

Documentation for Children 6 months through 5 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 Moderna COVID-19 Vaccine supplied in a multiple dose vial with a dark **blue** cap and a label with a magenta border for 6 months through 5 years**.** The carton labels state: **For age 6 months through 5 years.** For additional information, please refer to the CDPH COVID-19 vaccine Product Guide.

Moderna Pediatric (6 months through 5 years)

Packaging	
Vial cap color	Dark Blue
Doses per vial	10 doses
Carton Size	100 doses
Carton NDC #	80777-279-99
Administration	
Dose	25 micrograms
Injection volume	0.25 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 all Moderna Cap Formulations	
Freezer (-50°C to -15°C)	Until Published Expiration Date
Refrigerator (2°C to 8°C)	Up to 30 Days
Post puncture	12 hours

Vial Storage and Handling

Frozen Storage

Store frozen between -50°C to -15°C (-58°F to 5°F).

Storage after Thawing

- Storage at 2°C to 8°C (36°F to 46°F): Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use. Vials should be discarded 12 hours after the first puncture.
- Storage at 8°C to 25°C (46°F to 77°F):
  Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.
  Vials should be discarded 12 hours after the first puncture.
  Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

Do not refreeze once thawed.

Thawed vials can be handled in room light conditions.

Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F). If transport at -50°C to -15°C (-58°F to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2°C to 8°C (36°F to 46°F) when shipped using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.

REACTOGENICITY AND ADVERSE EVENTS

Available safety and immunogenicity data for Moderna COVID-19 Vaccines in children and adolescents are similar to those seen in young adults. Adverse reactions in individuals 6 months through 23 months of age following administration of the primary series included irritability/crying, pain at the injection site, sleepiness, loss of appetite, fever, swelling at the injection site, erythema at the injection site, and axillary (or groin) swelling/tenderness. Adverse reactions in individuals 24 months through 36 months of age following administration of the primary series included pain at the injection site, irritability/crying, sleepiness, loss of appetite, fever, erythema at the injection site, swelling at the injection site, and axillary (or groin) swelling/tenderness. Adverse reactions in individuals 37 months through 5 years of age following administration of the primary series included pain at the injection site, fatigue, headache, myalgia, fever,

chills, nausea/vomiting, axillary (or groin) swelling/tenderness, arthralgia, erythema at the injection site, and swelling at the injection site.

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 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 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 Moderna COVID-19 vaccines in children aged 6 months through 5 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 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 Moderna 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 Moderna COVID-19 Vaccine: Includes job aids for vaccine preparation, storage and handling, transport guidance, and more.

FDA Emergency Use Authorization Fact Sheet for Moderna COVID-19 Vaccine for 6 months through 5 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): Moderna COVID-19 Vaccine™ is covered by the federal VICP.

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