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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: MenQuadfi™ (MenACWY Vaccine) Available Through the VFC Program

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SUMMARY

This document summarizes information about the use of MenQuadfi™ in the California VFC program. On April 23, 2020, the United States (U.S.) Food and Drug Administration (FDA) approved the licensure of MenQuadfi™ (Sanofi Pasteur). MenQuadfi™ for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. MenQuadfi™ vaccine is approved for use in individuals 2 years of age and older.



The federal Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with a quadrivalent meningococcal conjugate vaccine (MenACWY) for adolescents aged 11 or 12 years, with a booster dose at age 16 years.

BACKGROUND AND COMPOSITION

MenQuadfi™ is composed of *Neisseria meningitidis* serogroups A, C, W and Y capsular polysaccharide antigens that are individually conjugated to detoxified tetanus toxoid protein (TT). MenQuadfi™ is supplied as a sterile, clear solution. Each 0.5 mL dose of vaccine contains 10 micrograms of each meningococcal A, C, W and Y polysaccharide antigens conjugated to approximately 55 micrograms tetanus toxoid protein carrier; 3.35 mg sodium chloride (0.67%), and 1.23 mg sodium acetate (30 mM). MenQuadfi™ and its vials do not contain thimerosal or latex.

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of MenQuadfi™

VFC supplies of MenQuadfi™ may be given to any VFC-eligible child ages 11 years through 18 years for primary and booster doses. VFC supplies of MenQuadfi™ may also be given to VFC-eligible children and adolescents 2 years through age 18 years who are at increased risk for meningococcal disease attributable to serogroups A, C, W, and Y, per the [VFC resolution](#).

Licensed Dosing Schedule

MenQuadfi™ is licensed to be given as a

- Primary vaccination
 - Single dose to individuals 2 years of age and older
- Booster vaccination
 - Single dose administered to individuals 15 years of age and older who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (Groups A, C, W, Y) conjugate vaccine.

Use of VFC vaccine for primary and booster immunization of children and adolescents recommended by [ACIP](#) is also permitted, as follows:

[ACIP recommends meningococcal](#) ACWY vaccine for:

- Routine vaccination as a 2-dose series at ages 11-12 years, with a booster at 16 years
- Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:
 - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart.

- Persons at increased risk, including travel in countries with hyperendemic or epidemic meningococcal disease, and first-year college students living in residential housing if not previously vaccinated or military recruits:
 - Children age 2 years or older: 1 dose
- See [ACIP recommendations](#) for further details

Contraindications

Severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi™ or any other tetanus toxoid-containing vaccine.

Precautions

Moderate or severe acute illness with or without fever.

MenACWY Vaccine Information Statement (VIS)

The most current version of the [Meningococcal ACWY Vaccine Information Statement](#) must be provided to a parent or guardian before the child receives each dose of the vaccine. Each time a VIS is provided the following information must be included in each patient's permanent medical record:

- (1) Edition date of the current Vaccine Information Statement that was provided.
- (2) Date that the VIS was provided.

A copy of the latest MenACWY VIS is attached.

Administration

0.5 mL dose for intramuscular injection.

Storage and Handling

MenQuadfi™ should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze.

Administration with Other Vaccines

MenQuadfi™ can be administered at the same visit as other recommended vaccines.

POTENTIAL VACCINE ADVERSE EVENTS

The most commonly reported adverse reactions following a primary and booster dose include: pain, erythema, or swelling at the injection site; malaise, myalgia and headache.

REPORTING OF SUSPECTED VACCINE ADVERSE EVENTS OR ERRORS

Providers should report suspected adverse events to MenQuadfi™ or any other vaccine to the Vaccine Adverse Events Reporting System (VAERS) at 800-822-7967 (toll-free) or <http://vaers.hhs.gov>.

Providers should report any vaccine administration error and associated contributing factors to the National Vaccine Errors Reporting Program (VERP) at

<http://verp.ismp.org/>. As a part of the report, providers can make recommendations to prevent errors. This surveillance program aims to prevent errors by identifying trends, creating targeted education, and changing product labeling and design.

HOW SUPPLIED

MenQuadfi™ is supplied in a single-dose vial in packages of 5 vials (NDC 49281-590-05)

ORDERING AND BILLING

VFC Ordering

MenQuadfi™ is now available for VFC Providers to order through their [MyVFCvaccines](#) account. The other MenACWY products listed in the table below are currently available for ordering through the California VFC Program.

<u>Vaccine</u>	<u>Trade Name</u>	<u>Manufacturer</u>	<u>Primary Series</u>	<u>Booster</u>
MenACWY	MenQuadfi™	Sanofi	11 to 12 years	16 years
MenACWY	Menactra®	Sanofi	11 to 12 years	16 years
MenACWY	Menveo®	GlaxoSmithKline	11 to 12 years	16 years

If your practice plans on switching to MenQuadfi™ from another vaccine product, submit a "[Provider Request Form to Update Vaccine Brand Products Administered](#)" to the VFC Program and keep the following information in mind:

- Careful consideration should be given when selecting alternative brands or products in order to minimize the impact on provider practices.
- Implementation of a different vaccine brand or product should be approved by your practice's medical director or Provider of Record.
- Staff should be thoroughly informed and educated on changes to vaccines and its impact on vaccine ordering, storage, administration, and documentation.
- As your practice transitions to a new product, managing on-hand inventory appropriately is a key factor in preventing unnecessary vaccine wastage. Your initial request for a new vaccine product may be reduced to help minimize vaccine waste as you transition from the product currently being used by your practice.
- A plan to deplete excess inventory must be in place prior to transitioning to a new product. It is the provider's responsibility to ensure all VFC-supplied vaccines are used prior to its expiration date or transferred to another VFC Provider who can use them. Viable unused doses of these individual vaccines cannot be returned to the VFC Program.

Billing Information for VFC Vaccine

CHDP:

Claims may be submitted for VFC-supplied doses of MenQuadfi™ administered to CHDP-eligible patients through age 18 years. Please refer to the CHDP Provider manual and relevant [CHDP Provider Information Notice](#).

CHDP providers with additional questions are advised to contact their [County CHDP Program](#) at <http://www.dhcs.ca.gov/services/chdp/Pages/CountyOffices.aspx>

Medi-Cal Fee-For-Service (FFS):

To bill Medi-Cal FFS for administration of VFC-supplied doses MenQuadfi™, use the appropriate CPT-4 code 90619, followed by the “-SL” modifier. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS eligible patients. The CPT code for administration of MenQuadfi™ by VFC providers for Medi-Cal is **90619-SL**.

For specific information and details on Medi-Cal billing, please refer to the [Medi-Cal provider manual on VFC](#). Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

Medi-Cal Managed Care

Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

Other codes for the use of MenQuadfi™ that is not supplied by VFC:

- The CPT-4 code for MenQuadfi™ is **90619**.
- The ICD-10-CM code for an encounter for immunization is **Z23**.

DOCUMENTATION

[Vaccine Information Statement \(VIS\)](#): The latest MenACWY VIS sheet can be found at <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening.html>. Additional information on vaccines and vaccine preventable diseases can be found at: <http://www.cdc.gov/vaccines/>.

[EZIZ Vaccine Fact Sheet](#): One-page, quick-reference fact sheet that provides information about schedules, minimum intervals, age ranges, administration routes, billing codes, storage, and more: <https://eziz.org/resources/vaccinefactsheets/>

[FDA Product Insert](#): Refer to the product package insert for MenQuadfi™ for additional vaccine information. This may be found at: <https://www.fda.gov/vaccines-blood-biologics/menquadfi>

[VFC Resolution No. 6/20-1 \(Vaccines to Prevent Vaccines To Prevent Meningococcal Disease\):](#)

The VFC resolutions for MenQuadfi™-containing vaccines may be found at: <https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>

[ACIP Meningococcal vaccine recommendations:](#) ACIP recommendations for MenACWY vaccine use are posted at <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html>.

[AAP vaccine recommendations](#) and other information about MenACWY vaccines are available to AAP members at <http://www.cispimmunize.org/> .

[General Recommendations on Immunization](#) (includes minimum ages and intervals) may be found at: <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>

[Vaccine Injury Compensation Program \(VICP\):](#) MenQuadfi™ is covered by the federal VICP. Information on the federal VICP and MenACWY vaccines may be found at: <http://www.hrsa.gov/vaccinecompensation/>.