

Office of Immunization and Child Profile VACCINE ADVISORY COMMITTEE Clinical Guidance on Meningococcal B Vaccine April 2019

In 2015, the Advisory Committee on Immunization Practices (ACIP) recommended meningococcal B (MenB) vaccine for patients at high risk for this disease and for outbreak control, but left it to providers' clinical discretion whether or not to advise it for others. These recommendations are available at:

https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6422a3.htm http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm.

These recommendations are challenging to implement because they require providers to consider the relevant evidence about the vaccines' safety, efficacy and duration of immunity, the risk of meningococcal B disease for a specific patient, and then formulate their advice and communicate it to parents and patients. Some members of the Vaccine Advisory Committee believe providers may have an ethical obligation to inform parents and patients of the availability of MenB vaccines, even if they would advise limiting their use to those at high risk of meningococcal B disease.

The Washington State Vaccine Advisory Committee is providing this guidance to:

- 1. Give providers current information on the incidence of meningococcal B disease in WA State.
- 2. Assist providers to formulate their own advice for communication with parents and patients about use of MenB vaccines in those who are not at high risk for the disease.

Considerations for Administering Meningococcal B Vaccine

Ten Year Incidence of Meningococcal B Disease

Serogroup B cases by age group among all reported meningococcal cases, Washington State, 2008-2017							
	Age Group (Years)						
	<2 n (%)	2-10 n (%)	11-15 n (%)	16-24 n (%)	25+ n (%)	All Ages	
Cases with an isolate available for testing*	46	24	5	34	85	194	
Cases due to Serogroup B	30 (65%)	10 (42%)	1 (20%)	11 (32%)	24 (28%)	76 (39%)	
Cases due to other serogroups	16 (35%)	14 (58%)	4 (80%)	21 (62%)	59 (69%)	114 (59%)	
Cases with non- groupable isolates	0	0	0	2 (6%)	2 (2%)	4 (2%)	
		*Isolates w	vere not available f	or 12 of the 206 cas	es that occurred du	ring this time frame	

^{*}Click here for the Washington Annual Communicable Disease Reports.

Meningococcal B disease in adolescents and young adults:

The meningococcal B disease burden of illness in adolescents and young adults is low in the US. It is hard to predict who will get the disease. In the U.S., there are about 35–55 cases each year in the 11 to 24-year-old age group who are eligible to receive the vaccine. The majority (>80%) of these cases occur in older adolescents and young adults aged 16–23 years. In Washington State, among 11 to 24 year olds, approximately 1 to 2 cases of meningococcal B disease are detected each year with most occurring in the 16-24-year-old age group, the age recommended for vaccine administration (see box above).

Meningococcal B disease in college students:

During 2014-2016, there were an estimated 60 meningococcal B cases among college students in the US, including. Of these cases, one third were related to outbreaks on college campuses, including deaths. The estimated incidence of meningococcal B disease in college students aged 18–24 years (0.17 per 100,000) was higher than the incidence in all persons aged 18–24 years (0.09 per 100,000) and non-college students aged 18–24 years (0.05 per 100,000). (Source: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2018-02/Mening-02-Meyer-508.pdf)

Effectiveness:

Both vaccines induce an immune response against most, but not all, circulating B strains. No studies have been performed to evaluate the effectiveness of the vaccine in preventing meningococcal B disease.

Duration of Immunity:

The vaccines induce immunity that persists in most recipients for 48 months after vaccination; the full duration of immunity is unknown.

Safety:

There is limited experience with MenB vaccines outside of clinical trials. Theoretical safety concerns include the possible development of an autoimmune response. Post-licensure safety surveillance will be important in determining the safety profile for less frequent adverse events. Other vaccine reactions may include syncope, local inflammation at site of injection, fatigue, headaches, and anaphylaxis.

ACIP Recommendations for MenB Vaccine:

The ACIP agreed that historically low levels of disease, limited data about the lasting effectiveness of the vaccine, and potentially high costs don't warrant routinely vaccinating all children with MenB vaccine.

The vaccine <u>should be</u> administered to persons ≥10 years of age who are at increased risk for meningococcal B disease and its complications, including:

- Persons with persistent complement component deficiencies (including eculizumab use).
- Persons with anatomic or functional asplenia, including sickle cell disease.
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
- Persons identified as at increased risk because of a serogroup B meningococcal disease outbreak.

Patients 16 through 23 years of age <u>may be</u> vaccinated with MenB vaccine (preferably at 16 through 18 years of age) to provide short-term protection against most strains of serogroup B meningococcal disease.

Suggestions for Talking Points with Parents for Patients Not at Increased Risk for Meningococcal B Infection:

- MenB vaccine is recommended for those at high risk for meningococcal B disease.
 - Persons ≥10 years of age who are at increased risk for meningococcal B disease and its complications, including:
 - Persons with persistent complement component deficiencies (including eculizumab use).
 - Persons with anatomic or functional asplenia, including sickle cell disease.
 - Microbiologists routinely exposed to isolates of Neisseria meningitidis
 - Persons identified as at increased risk because of a serogroup B meningococcal disease outbreak.
- If your child does not have specific risk factors, they are not at high risk for contracting Meningococcal B.
- Although your child is not at high risk and the disease is rare, the potential benefits of the vaccine may
 outweigh the risk for your child. I will give your child the vaccine if you want them to have it.

Meningococcal Vaccine Types:

The table below provides a summary of the two licensed meningococcal B vaccines.

Characteristic	Bexsero	Trumenba
Manufacturer	GlaxoSmithKline Pharmaceuticals (GSK)	Wyeth (Pfizer) Pharmaceuticals
Licensure	10 through 25 years	10 through 25 years
Schedule	Two doses, at least one month apart (0 & ≥1 month schedule)	Two doses (0 & 6 months) High risk: Three doses (0, 1-2, and 6 month schedule)
Interchangeability	Must complete series with same product	Must complete series with same product
CPT / CVX Codes	90620 / 163	90621 / 162

https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6619a6.pdf

Nothing in this guidance supersedes the recommendations of the ACIP. Providers should review the complete <u>ACIP recommendations</u> for use of meningococcal vaccines for additional details regarding available vaccine products, indications, and precautions or contraindications.

Ordering from the State Department of Health

Providers enrolled in the Washington State Childhood Vaccine Program (CVP) may order MenB vaccine directly from the state as needed. Providers should order sufficient vaccine to complete the series for the patient with the same product.

Contact information for state staff to assist with order placement:

- Phone: 360-236-2VAX (2829) ask to speak with someone about ordering MenB vaccine.
- E-mail: WAChildhoodVaccines@doh.wa.gov

For more information:

Meningococcal Vaccination:

http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.html

Prevention and Control of Meningococcal Disease:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm#Box1

ACIP MenB Vaccine Recommendation:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm