

Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥ 10 Years

1. Recommendations

2. Vaccine Availability and Ordering

August 2015

1. Recommendations

In October 2014, the Food and Drug Administration (FDA) licensed the first serogroup B meningococcal (MenB) vaccine (MenB-FHbp), Trumenba by Pfizer, as a 3-dose series. In January 2015, the FDA licensed a second MenB vaccine (MenB-4C), Bexsero by GlaxoSmithKline (GSK), as a 2-dose series. Both MenB vaccines were approved for use in persons aged 10–25 years. However, the ACIP has made an off-label recommendation for their use in certain persons aged ≥ 10 years who are at increased risk for meningococcal disease, see below.

a. Recommendations for Use in Certain High Risk Individuals

The Advisory Committee on Immunization Practices (ACIP) [recommendations](#) for use of MenB vaccines in groups at increased risk for serogroup B meningococcal disease have been published (CDC. MMWR 2015;64:608-612). This recommendation was designated Category A (recommended for all persons in an age-based or risk-factor-based group). The ACIP has made an off-label recommendation for the use of both MenB vaccines in certain persons aged ≥ 10 years who are at increased risk for meningococcal disease due to serogroup B. These groups include:

- Persons with persistent complement component deficiencies (including: inherited or chronic deficiencies in C3, C5-9, properdin, factor D, factor H, or taking eculizumab [Soliris[®]].)
- Persons with anatomic or functional asplenia (including: sickle cell).
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*.
- Persons identified as at increased risk because of a serogroup B meningococcal disease outbreak.

MenB vaccines are not recommended for persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic because meningococcal disease in these countries generally is not caused by serogroup B.

b. Considerations for Use in Adolescents and Young Adults

At its June 2015 meeting, the ACIP recommended that a MenB vaccine series *may* be administered to adolescents and young adults 16 through 23 years of age to provide short term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination in this age group is 16 through 18 years of age in order to maximize protection during the highest risk period.

This recommendation was designated Category B (recommended for individual clinical decision making). The ACIP approved a Category B recommendation for 2 main reasons. First, the current burden of disease is low which means that the number needed to vaccinate to prevent a case and death is high. Secondly, because the MenB vaccines were recently licensed for use in the U.S. under an accelerated approval process, complete data for making policy recommendations for MenB vaccines are not yet available about: the true proportion of serogroup B disease that could be prevented by vaccine; vaccine effectiveness and duration of protection; impact on carriage and herd immunity.

The slides from the June ACIP meeting can be found at <http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html>. However, recommendations for this age group have not yet been published. When they are, they will be found at <http://www.cdc.gov/vaccines/acip/>; and we will share them with you.

c. Vaccine Schedules

- Bexsero (MenB-4C) should be administered as a 2-dose series (0, ≥ 1 month).
- Trumenba (MenB-FHbp) should be administered as a 3-dose series (0, 2, 6 months).
- The same vaccine product must be used for all doses.
- Based on available data and expert opinion, MenB-FHbp or MenB-4C may be administered concomitantly with MenACWY vaccines and other adolescent vaccines, but at a different anatomic site, if feasible.

Please note: MenB vaccines are not licensed or recommended for children aged < 10 years.

(over)

The table below provides additional information about the vaccines and their schedules.

Meningococcal Group B Vaccines

Vaccine/ Manufacturer	Antigen Content	Schedule
MenB-FHbp (Trumenba) Pfizer	Components: Two highly conserved variants of factor H binding protein (FHbp) subtypes: subfamily A/v2,3 subfamily B/v1	0, 2, 6 mos
MenB-4C (Bexsero) GSK	Components: Factor H binding protein (FHbp) subfamily B/v1 Neisserial adhesion A (NadA) Neisserial heparin binding antigen (NHBA) Outer membrane vesicles (OMV) containing PorA P1.4	0, ≥1*

*In some studies, doses of MenB-4C were administered up to 6 months apart.

Package Inserts from FDA Website: [Trumenba](#) and [Bexsero](#)

2. Vaccine Availability and Ordering

Because MenB vaccine is not currently in your inventory, you will need to perform an additional step the first time you order this vaccine. You will need to select “Add Vaccine from Formulary” at the bottom of the screen after you request doses of the other vaccines you are ordering. Under “Vaccine”, there is a drop down menu.

- If you want to order Bexsero®, you will need to select MenB-4C – Bexsero
- If you want to order Trumenba®, you will need to select MenB-FHbp – Trumenba

Only select one formulation. Indicate how many doses you want as an initial inventory. Bexsero® can be ordered in single-pack syringes. Trumenba® can only be ordered in 10-pack syringes. The vaccine will appear in your inventory after you receive the vaccine shipment and you will not have to perform this additional step when you place your subsequent orders.

NOTE: As outlined above and in the *Childhood Vaccine Availability Table*, MenB vaccine:

- 1) is universally available for a very small group of high-risk adolescents 10 through 18 years of age and**
- 2) may be considered for VFC-eligible adolescents 16 through 18 years of age (permissive recommendation).**

Vaccine Information Statement (VIS)

A VIS entitled “Serogroup B Meningococcal Vaccine (MenB): What You Need to Know” (dated 8/15/2015) is available at <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.pdf>.

Questions

For questions about state supplied **vaccine availability and ordering**, please contact the Vaccine Management Unit at 617-983-6828. For questions about **MenB vaccine recommendations**, please call the Immunization Program at 617-983-6800 and ask to speak to an immunization epidemiologist or immunization nurse. When additional guidance about MenB vaccines is available, we will share it with you.