



<u><b>MenB Primary Series Schedule</b></u>		
<b>Bexsero® (MenB-4C)</b>	<b>Trumenba® (MenB-FHbp) – 3 Dose</b>	<b>Trumenba® (MenB-FHbp) – 2 Dose</b>
Dose 1: 0 months	Dose 1: 0 months	Dose 1: 0 months
Dose 2: 1 month	Dose 2: 1 – 2 months	Dose 2: $\geq 6$ months
	Dose 3: 6 months ( $\geq 4$ months between Dose 2 & 3)	



## Clinical Frequently Asked Questions – July 29, 2019

Outbreak of Serogroup B Meningococcal Disease Associated with Rutgers University – New Brunswick, 2019

### **How many cases of meningococcal disease are associated with Rutgers University – New Brunswick?**

The New Jersey Department of Health (NJDOH), Middlesex County Office of Health Services, and Rutgers Student Health continue to investigate an outbreak of invasive *Neisseria meningitidis* – serogroup B associated with Rutgers University – New Brunswick. The first case became ill on February 3 and the second case became ill on February 19. Both have since recovered. Close contacts were identified and recommended to receive prophylactic antibiotics.

### **Are the organisms from the two cases the same?**

Specimens from the two cases were sent to the Centers for Disease Control and Prevention (CDC) for molecular testing. The ability to test the specimens was limited since bacterial isolates were not available for either case. Nevertheless, the CDC determined that the two cases were caused by strains from the same clonal complex, a clonal complex that is uncommon among cases of invasive meningococcal disease. Additionally, the typing genes were identical between the two organisms. The organisms identified in these two cases are not closely related to the organisms involved in the 2016 outbreak of meningococcal disease associated with Rutgers University – New Brunswick.

### **I understand that public health officials are recommending a booster dose of serogroup B meningococcal (MenB) vaccine as part of the outbreak response. Why is a booster being recommended?**

Immunity following receipt of MenB is short-lived. Evidence presented to Advisory Committee on Immunization Practices (ACIP) suggests that vaccine recipients who completed a previous MenB vaccine series  $\geq 1$  year prior may no longer be protected against serogroup B meningococcal disease. For these individuals, a booster dose may be needed for protection during the outbreak. If a booster dose is given, the booster should be the same product used to complete the primary series. In June 2019, the ACIP officially voted to include booster dose recommendations. If the CDC director approves the recommendation, it will be published as official recommendations in the *Morbidity and Mortality Weekly Report*. A summary of the ACIP recommendations is available through the American Academy of Pediatrics website at: <https://www.aappublications.org/news/2019/06/28/acip062819>

As insurance coverage for vaccination is based on ACIP recommendations, please check to be sure insurance will cover the booster dose of the MenB vaccine.

### **Which groups at Rutgers University – New Brunswick are recommended to receive MenB vaccine?**

The NJDOH, in consultation with CDC, is continuing to recommend MenB vaccination of the following at-risk populations at Rutgers University – New Brunswick:

- All current and incoming undergraduate students including transfer students, regardless of whether they live in on-campus housing
- All individuals (including graduate students) who live in undergraduate on-campus housing

- All graduate students, faculty, and staff with medical conditions placing them at increased risk for meningococcal disease or microbiologists routinely exposed to *Neisseria meningitidis* as per usual ACIP recommendations. The high-risk conditions include:
  - Having complement deficiency
  - Taking Soliris® (eculizumab)
  - Having functional or anatomic asplenia

Students at highest risk include for meningococcal disease include:

- Students who are active in Greek life
- Students living in on-campus housing
- Individuals with high-risk conditions as indicated above

**Which vaccines are being recommended to provide protection to at-risk populations during this outbreak?**

Two vaccines provide protection against serogroup B meningococcal disease: Bexsero® (GlaxoSmithKline – MenB-4C) and Trumenba® (Pfizer – MenB-FHbp). In the setting of an outbreak, CDC recommends either two doses of Bexsero® or three doses of Trumenba®. It does not matter which brand someone receives. People should get the same vaccine brand for all doses — Bexsero® and Trumenba® are not interchangeable. If someone decides to switch brands, CDC recommends waiting at least 1 month between products and then getting the full series of the other vaccine product.

**Why should Trumenba® be administered as a 3-dose series instead of a 2-dose series in this situation?**

The 3-dose regimen is recommended in order to rapidly induce immunity in persons at increased risk for meningococcal disease during outbreaks. Please note that persons who received 2 doses of Trumenba® administered at 0 and 6 months may be considered to have completed a primary series. However, if the 2<sup>nd</sup> dose was given at an interval of less than 6 months from the 1<sup>st</sup> dose, a 3<sup>rd</sup> dose should be given at least 4 months after the 2<sup>nd</sup> dose.

**I have an unvaccinated student who needs MenB as part of the outbreak response. How should I proceed?**

You should initiate MenB series and follow-up as appropriate to ensure completion of the series. In the setting of an outbreak, CDC recommends either two doses of Bexsero® or three doses of Trumenba®. It does not matter which brand someone receives. People should get the same vaccine brand for all doses — Bexsero® and Trumenba® are not interchangeable. If someone decides to switch brands, CDC recommends waiting at least 1 month between products and then getting the full series of the other vaccine product.

**What if the individual does not have documentation of which vaccine product (Bexsero® or Trumenba®) they previously received, and you need to administer additional doses?**

People should get the same vaccine brand for all doses — Bexsero® and Trumenba® are not interchangeable. If you do not know what brand was previously received, you should administer a complete primary series of either Bexsero® and Trumenba® CDC recommends either two doses of Bexsero® or three doses of Trumenba®. If someone decides to switch brands, CDC recommends waiting at least 1 month between products and then getting the full series of the other vaccine product.

**I have a patient whose first dose was Trumenba® but the second dose was Bexsero®. How should I proceed with completing the MenB vaccination series? We stock both vaccines.**

The ACIP meningococcal serogroup B vaccine recommendations

([www.cdc.gov/mmwr/pdf/wk/mm6441.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6441.pdf), pages 1171–6) state that the same vaccine must be used for all doses in the MenB series. So the clinician needs to complete a series with one or the other vaccine. If a person has already received 1 dose of Bexsero<sup>®</sup> and one of Trumenba<sup>®</sup>, then choose one brand and finish the recommended schedule with that brand. Ignore the extra dose of the other product. In this scenario, the next dose in the series (either Trumenba<sup>®</sup> or Bexsero<sup>®</sup>) should be separated from the previous dose of Bexsero<sup>®</sup> by at least 1 month.

### **What adverse events may occur after receiving MenB?**

In clinical trials the most common adverse events within 7 days of receiving MenB were injection site pain, swelling or redness (80%–90% of recipients). Up to 30% of recipients considered the pain to be severe. Other reported symptoms included fatigue (35%–40%), headache (33%–35%), and myalgia (30%–49%). In general, adverse events were more frequent with the first dose than with subsequent doses.

### **What are the contraindications and precautions for MenB?**

As with all vaccines, a severe allergic reaction (for example, anaphylaxis) to a vaccine component or to a prior dose is a contraindication to further doses of that vaccine. The tip caps of the Bexsero<sup>®</sup> pre-filled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. A moderate or severe acute illness is a precaution; vaccination should be deferred until the person's condition has improved. Because MenB is an inactivated vaccine it can be administered to persons who are immunosuppressed as a result of disease or medications; however, response to the vaccine might be less than optimal.

### **Can a pregnant woman receive MenB vaccine?**

Few data are available on the effect of MenB vaccines on pregnancy. The manufacturers do not consider pregnancy to be a contraindication to use of MenB. GlaxoSmithKline has established a Vaccination in Pregnancy registry. Women who receive Bexsero<sup>®</sup> during pregnancy are encouraged to participate in the registry by calling 877-683-4732. Pfizer has not established a Vaccination in Pregnancy registry for Trumenba<sup>®</sup>.

Additional resources:

Rutgers Student Health

<http://health.rutgers.edu/meningitis/>

NJDOH

<https://www.nj.gov/health/cd/topics/meningo.shtml>

Directory of Local Health Departments in New Jersey

<https://www.nj.gov/health/lh/community/index.shtml>

CDC

<http://www.cdc.gov/meningococcal/>

Immunization Action Coalition

<http://www.immunize.org/>

July 29, 2019