Standing Orders for Administering Meningococcal Group B Vaccine (Adult)

Purpose: To reduce morbidity and mortality from serogroup B meningococcal disease by vaccinating all persons who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) product labeling, and the Department of Defense (DoD).

Policy: Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:
1. Identify persons 18 – 25 years of age in need of vaccination against serogroup B meningococcal disease based on the following criteria:
   - Persons 18 – 25 years of age with:
     - Diagnosis of persistent complement component deficiency (e.g., deficiencies in C3, C5-9, factor D, factor H, or properdin)
     - Anatomic or functional asplenia
     - Taking eculizumab (Soliris®) or ravulizumab (Ultomiris®)
     - Laboratory staff routinely exposed to Neisseria meningitides
     - Increased risk due to serogroup B meningococcal disease outbreak
   - Persons 18 – 23 years of age not at increased risk who want protection against serogroup B meningococcal disease*

   *Note: the decision to vaccinate persons not at increased risk should be based on shared clinical decision-making: these patients should speak with a privileged provider before vaccination

2. Screen all patients for contraindications and precautions to serogroup B meningococcal vaccine (MenB):
   - Contraindications:
     - A history of a serious reaction (e.g., anaphylaxis) after a previous dose of MenB or to a vaccine component (to include kanamycin)
     - For information on vaccine components, refer to the manufacturer’s package insert or go to http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf
   - Precautions:
     - Moderate or severe acute illness with or without fever
     - The tip caps of the prefilled syringes of Bexsero® contain natural rubber latex and may cause allergic reactions in latex sensitive individuals. Trumenba® does not contain latex
     - Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid a falling injury (e.g. 15 minute observation after administration) and to restore cerebral perfusion following syncope
     - For questions or concerns, consider consulting the DHA Immunization Healthcare Division at (877) 438-8222, Option 1 or DSN 761-4245

Reviewed by DHA-IHD June 2020
Note: available data are not sufficient to assess the effects of MenB on persons who are pregnant or nursing. MenB should be used during pregnancy or nursing only if benefit clearly outweighs risk, and is not covered under this standing order. Patients must obtain a written order from a privileged provider for this situation

3. Provide all patients (or their parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient’s medical record, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.

4. Provide vaccine as follows:
   - Follow dosing schedule in table below
   - Administer 0.5mL intramuscularly in the deltoid muscle for adults

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bexsero¹ (MenB-4c, GlaxoSmithKline)</td>
<td>0.5mL</td>
<td>Two doses, 4 weeks apart²,³</td>
</tr>
<tr>
<td>Trumenba¹ (MenB-FHbp, Pfizer)</td>
<td>0.5mL</td>
<td>Two doses at 0 and 6 months²,⁴</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Three doses at 0, 1–2, and 6 months³</td>
</tr>
</tbody>
</table>

¹The two brands of MenB vaccine are not interchangeable: the series must be started and completed with the same brand of vaccine
²The 2-dose schedules of either Bexsero or Trumenba may be used in healthy persons
³Either the 2-dose schedule of Bexsero or the 3-dose schedule of Trumenba should be given to persons at increased risk for meningococcal serogroup B disease
⁴If Dose #2 of the 2-dose Trumenba series is administered earlier than 6 months after Dose #1, a third dose should be administered at least 4 months after Dose #2.

Note: ACIP recommends:
   - For persons aged ≥10 years with complement deficiency, complement inhibitor use, asplenia, or who are laboratory staff:
     - Booster dose 1 year following completion of a MenB primary series followed by booster doses every 2-3 years as long as increased risk remains
• For persons aged ≥10 years determined by public health officials to be at increased risk during an outbreak:
  o One-time booster dose if it has been ≥1 year since completion of a MenB primary series

These recommendations are off-label uses of the vaccine and are not covered under these standing orders. Patients must obtain a written order from a privileged provider for these situations

5. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.

6. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.

7. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (800-822-7967) or online at https://vaers.hhs.gov.

8. This policy and procedure shall remain in effect for all patients of the _______________________________ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

_________________________________________                    __________________________
Medical Director’s Signature                      Date