Meningococcal Conjugate (Groups A, C, Y and W-135) Vaccine Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.281**
Created by:	Provincial Immunization Program Standards and Quality		
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	Nimenrix®	**Menveo®**	**Menactra®**
Manufacturer	Pfizer Canada Inc	GlaxoSmithKline	Sanofi Pasteur Limited
Biological Classification	Inactivated Conjugate		

Indications for Provincially Funded Vaccine	**Pre-exposure:**
	2 months up to and including 23 months of age at high risk for invasive meningococcal disease (IMD) including the following – use **Menveo®** vaccine only:
	• Asplenia - anatomical or functional (including sickle-cell disease).
	• Acquired complement deficiency (e.g., due to receipt of the terminal complement inhibitor eculizumab [Soliris®]).
	  ○ Note: Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose of Soliris® if possible.
	• Congenital complement, properdin, factor D or primary antibody deficiencies.
	• HIV infection especially if it is congenitally acquired.
	• Hematopoietic stem cell transplant (HSCT) recipients - see *Standard for Immunization of Transplant Candidates and Recipients.*
	• Solid organ transplant (SOT) candidates and recipients.
	  ○ To determine eligibility, appropriate vaccine and schedule see *Standard for Immunization of Transplant Candidates and Recipients.*
	2 years and older:
	• Students in grade 9 – routine program in Alberta.
	  ○ Students should receive the vaccine regardless of previous meningococcal immunization received in a **routine infant/preschool program**.
	  ○ Students in ungraded classes or those who do not continue in the school system to grade 9 can still be immunized on a case by case basis, generally at 14 years up to and including 18 years of age.
	  ○ The guiding principle should be to offer protection to students prior to them leaving the school system.
	  ○ Students who were eligible in Grade 9 (starting in 2010-2011 school year) but did not receive the vaccine, continue to be eligible to receive this vaccine up to the end of Grade 12 if they present to public health.
	• Individuals at **high risk for invasive meningococcal disease** including the following:
	  ○ Asplenia - anatomical or functional (including sickle-cell disease).
	  ○ Acquired complement deficiency (e.g., due to receipt of the terminal complement inhibitor eculizumab [Soliris®]).
	  ▪ **Note:** Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose of Soliris® if possible.
	  ○ Congenital complement, properdin, factor D or primary antibody deficiencies.
	  ○ HIV infection especially if it is congenitally acquired.
	  ○ Hematopoietic stem cell transplant (HSCT) recipients see *Standard for*		

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	Immunization of Transplant Candidates and Recipients. ○ Solid organ transplant (SOT) candidates and recipients. ▪ To determine eligibility, appropriate vaccine and schedule see *Standard for Immunization of Transplant Candidates and Recipients*. • Laboratory workers routinely exposed to *Neisseria meningitidis*, if they are involved in conducting subculture identification, susceptibility testing, serological and/or molecular characterization and deep freeze for storage. Laboratory workers who do only initial specimen plants are not eligible. **Note:** Case-by-case assessment is required for immunization of individuals who are immune compromised. Medical consultation with the attending physician/infectious-disease specialist is strongly recommended.		
	Post-exposure: • Close contacts and/or outbreak control when serogroups A, Y, or W-135 are identified. **Notes:** • Immunization for outbreak control may continue beyond the closure of an outbreak when recommended by the Chief Medical Officer of Health. • Results of index case serogroup should be known (generally within 2 to 5 days) before proceeding with immunization. • Contacts under 2 years of age should receive Menveo® on the recommendation of NACI. • Contacts of meningococcal serogroup C who are eligible for meningococcal conjugate quadrivalent vaccine (MenC-ACYW) e.g., students in Grade 9, 10, 11 or 12 who have not already received their adolescent dose of MenC-ACYW vaccine, should receive MenC-ACYW not meningococcal conjugate C vaccine (MenconC). • Other contacts of meningococcal serogroup C – see *Meningococcal Conjugate (Group C) Vaccine Biological Pages*. • Contacts of meningococcal serogroup B see *Meningococcal B Multicomponent Recombinant Vaccine - BEXSERO®* • If the contact is eligible for post-exposure vaccine and has previously received polysaccharide meningococcal vaccine, a dose of Men C-ACYW may be indicated. For disease information, contact assessment, chemoprophylaxis and reporting guidelines refer to *Alberta Health, Public Health Notifiable Disease Management Guidelines – Meningococcal Disease, Invasive.*		
Schedule	**For SOT Candidates and Recipients and HSCT Recipient schedule,** including number of doses and boosters recommended refer to *Standard for Immunization of Transplant Candidates and Recipients.*		
	Pre-exposure: **Individuals at high risk of invasive meningococcal disease:** • **2 months up to and including 11 months – use Menveo® vaccine only:** ○ Dose 1 – 2 months of age (first dose should not be administered before 8 weeks of age) ○ Dose 2 – 4 months of age (and at least 4 weeks from dose 1) ○ Dose 3 – 6 months of age (and at least 4 weeks from dose 2) ○ Dose 4 – 12 months of age (and at least 8 weeks from dose 3) ○ Booster doses – 3 years after dose 4 and every 5 years as long as risk continues **Note:** Meningococcal conjugate C vaccine (MenconC) is not recommended in addition to Menveo® for infants and children at high risk of invasive meningococcal disease. • **12 months up to and including 23 months of age – use Menveo®vaccine only:** ○ 2 doses at least 8 weeks apart ○ Booster dose 3 years after dose 2 and every 5 years as long as risk continues		

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	• **2 years of age and older – <u>all vaccines</u>:**
	  ○ 2 doses administered at least 8 weeks apart
	  ○ Booster doses:
	  ▪ 6 years of age and younger at time of initial immunization, administer a booster dose 3 years after the last dose, followed by a booster every 5 years as long as risk continues.
	  ▪ 7 years of age and older at time of initial immunization, administer a booster dose every 5 years as long as risk continues.
	Notes:
	• The interval between doses may be shortened to four weeks if accelerated immunization is indicated.
	• Individuals at high risk for IMD, who previously received one dose of MenC-ACYW should receive a second dose of MenC-ACYW vaccine and booster doses as outlined above.
	• Individuals at high risk for IMD, who previously received meningococcal **polysaccharide** vaccine and continue to be at high risk for IMD, should be re-immunized with the appropriate MenC-ACYW vaccine. The interval between the polysaccharide vaccine and the MenC-ACYW should be at least 6 months. Booster doses of MenC-ACYW should be administered as outlined above.
	• When meningococcal conjugate C vaccine (MenconC) has been administered previously, the minimum interval between MenC-ACYW and MenconC should be at least 4 weeks.
	• It is preferable to give vaccine at least 14 days prior to splenectomy. In the case of an emergency splenectomy, vaccine should be given 14 days after the splenectomy. If the client is discharged earlier and there is concern that he/she might not return immunization should be given prior to discharge. Case by case consultation with the treating physician and MOH is recommended if there will be less than 14 days between vaccine administration and splenectomy.
	• Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose if possible.
	Grade 9 students:
	• 1 dose
	• The need for reinforcing doses of MenC-ACYW has not been established at this time.
	Notes:
	Students who have previously received MenC-ACYW:
	  ○ If MenC-ACYW vaccine was received when younger than 12 years of age – offer a dose in grade 9.
	  ○ If MenC-ACYW vaccine was received at 12 years of age or older – the vaccine is not indicated in grade 9.
	Eligible Laboratory Workers:
	• 1 dose
	• Booster doses every 5 years as long as risk continues.
	Notes:
	• For individuals who have previously received the meningococcal **polysaccharide** vaccine there should be at least a 6 month interval before administering MenC-ACYW.
	• When meningococcal C conjugate vaccine (MenconC) has been administered previously, the minimum interval between MenC-ACYW and MenconC should be at least 4 weeks.		

	<u>Post-Exposure or Outbreak Control (contacts of serogroups A, Y and W-135)</u>: **2 months up to and including 11 months of age –** use **<u>Menveo® vaccine only</u>:** • **Unimmunized:** ○ 3 doses administered 8 weeks apart with another dose between 12 and 23 months of age and at least 8 weeks from the previous dose. • **Previous immunization with MenconC:**		

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	○ Administer Menveo® series as for unimmunized regardless of when the last dose was administered. • **Previous immunization with MenC-ACYW:** ○ Administer 1 dose Menveo® if at least 4 weeks after a previous dose and complete the series. **12 months up to and including 23 months of age - <u>Menveo® vaccine only</u>:** • **Unimmunized:** ○ 2 doses of Menveo® with an interval of at least 8 weeks between doses. • **Previous immunization with MenconC:** ○ Administer 2 doses of Menveo® with an interval of at least 8 weeks between the doses regardless of when the previous dose of MenconC was administered. • **Previously immunized with MenC-ACYW:** ○ At younger than 1 year of age or at high risk for IMD due to underlying medical condition, administer 1 dose of Menveo® if at least four weeks since last dose. Otherwise, re-immunize if at least one year since the last dose of MenC-ACYW. ○ At 1 year of age or older and with no high-risk condition, administer 1 dose of Menveo® at least 1 year since the last dose of MenC-ACYW. **2 years of age and older – <u>all vaccines</u>:** • **Unimmunized:** ○ 1 dose • **Previously immunized with MenconC:** ○ Administer 1 dose of MenC-ACYW regardless of when the last dose of MenconC was administered. • **Previously immunized with MenC-ACYW:** ○ At younger than 1 year of age, administer 1 dose of MenC-ACYW if at least 4 weeks since the last dose. ○ At high-risk of IMD due to underlying medical condition, administer 1 dose of MenC-ACYW if at least 4 weeks since the last dose. ○ At 1 year of age or older and not at high-risk of IMD due to an underlying medical condition, administer 1 dose of MenC-ACYW if at least 1 year since the last dose of MenC-ACYW.		
Preferred Use	Individuals 2 months up to and including 23 months of age at high risk of invasive meningococcal disease or who are eligible contacts of a case will be offered **Menveo® vaccine only.** For individuals 2 years of age and older there will be no preference indicated for the use of meningococcal conjugate groups A, C, Y, W-135 vaccine in specific age or risk groups. • All vaccines are safe and immunogenic in individuals 2 years of age and older. • Persons with medical contraindications to one product should be offered the alternate product if supply is available.		
Dose	0.5 mL For Menveo®**,** withdraw the entire contents of the diluent (liquid MenCWY) and inject into the vial containing the powder (MenA). Shake vigorously in order to mix. Once reconstituted withdraw 0.5 mL from the vial and administer. For Nimenrix®, reconstitute by adding entire contents of the pre-filled syringe of diluent to the vial containing the powder. Mixture should be well shaken until powder is completely dissolved. Once reconstituted withdraw the contents from the vial and administer. For Menactra®, shake vaccine well until a uniform, clear to slightly turbid liquid is obtained. Withdraw total volume of 0.5 mL and administer.		
Route	IM		
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reactions to a previous dose of a vaccine containing similar components.		

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	Precautions: • Will not protect against infections caused by organisms other than serogroups A, C, Y and W-135 *N. meningitidis*. **Note:** NACI now recommends that Menactra® or Menveo® may be administered to people with a previous history of Guillain-Barré Syndrome (GBS). A previous history of GBS is not a contraindication to receiving Nimenrix®.		
Possible Reactions	**Common:** • Pain, redness, swelling, induration, or hematoma at the injection site. • Fever, chills • Irritability, fatigue, drowsiness, persistent crying, malaise • Headache, myalgia, arthralgia • Vomiting, nausea, diarrhea, decreased appetite, • Rash, hives **Uncommon:** • Induration, warmth, anesthesia at the injection site • Insomnia • Hypoesthesia • Dizziness • Pruritus **Rare:** • Anaphylaxis, allergic reaction. • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.		
Pregnancy	Adequate data is not available for the use of MenC-ACYW vaccine during pregnancy and therefore will not routinely be recommended in Alberta for pregnant women. However, use of this vaccine during pregnancy may be considered in consultation with your MOH based on the individual's risk of disease (e.g., post exposure) versus benefit of the vaccine.		
Lactation	Can be administered to eligible breastfeeding women.		
Composition	Provided as one vial (powder) of lyophilized Men ACYW-135 Conjugate Component and diluent (sodium chloride and sterile water) in a pre-filled syringe. **Each 0.5 mL dose of vaccine after reconstitution contains:** • 5 mcg *Neisseria meningitidis* serogroup A polysaccharide • 5 mcg *Neisseria meningitidis* serogroup C polysaccharide • 5 mcg *Neisseria meningitidis* serogroup W-135 polysaccharide • 5mcg *Neisseria meningitidis* serogroup Y polysaccharide • 28 mg sucrose • 97 mcg trometamol • 4.5 mg sodium chloride	Provided as one vial (powder) of lyophilized Men A Conjugate Component and one vial (liquid) of Men CWY Conjugate Component. **Each 0.5 mL dose of vaccine after reconstitution contains:** • 10 mcg Men A oligosaccharide 5 mcg Men C oligosaccharide • 5 mcg Men W-135 oligosaccharide • 5 mcg Men Y • 5 (mM) potassium dihydrogen phosphate • 4.5 mg sodium chloride • 12.5 mg sucrose • 10 mM sodium phosphate buffer • 7.5 mM di-sodium hydrogen phosphate bihydrate • 2.5 mM sodium	**Each 0.5 mL dose of vaccine contains:** • 4 mcg group A meningococcal polysaccharide • 4 mcg group C meningococcal polysaccharide • 4 mcg group Y meningococcal polysaccharide • 4 mcg group W-135 meningococcal polysaccharide • 4.25 mg sodium chloride • QS phosphate 10 mM (sodium phosphate, dibasic, anhydrous; and sodium phosphate, monobasic) • QS 0.5 mL water (for injection) Preservative-free and no adjuvant

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	• QS to 0.5 mL water for injections Preservative free and no adjuvants **Note:** The *Neisseria meningitidis* serogroups A and C polysaccharides are conjugated with an adipic dihydrazide (AH) spacer and indirectly conjugated to the tetanus toxoid whereas the W-135 and Y polysaccharides are conjugated directly to tetanus toxoid.	dihydrogen phosphate monohydrate • Water for injection q.s. 0.5 mL Preservative-free and no adjuvant **Note**: The meningococcal oligosaccharides are each conjugated to the *C. diphtheriae* CRM_{197} protein.	**Note:** The polysaccharide antigens are individually conjugated to diphtheria toxoid protein.
	For a detailed list of ingredients see the link below to the Canadian Immunization Guide: http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php		
Blood/Blood Products	Does not contain human blood/blood products		
Bovine/Porcine Products	Does not contain bovine or porcine products.	The manufacturing process involves some animal derivative.	• Components of bovine origin are used early in the manufacturing process. • Components of porcine origin are used early in the manufacturing process.
Latex	Does not contain latex.		
Interchangeability	• When possible the series should be completed using the same vaccine. For individuals 2 years of age and older, when the same vaccine is not available for the entire series, vaccine can be used interchangeably. Booster doses may be administered using either vaccines. • For individuals under 2 years of age only Menveo® should be used.		
Administration with Other Products	May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine. The same limb may be used if necessary, but different sites must be chosen.		
Appearance	After reconstitution, vaccine is a clear, colorless solution.	After reconstitution, vaccine is a clear, colourless solution.	Menactra® is a sterile, clear to slightly turbid liquid.
Storage	• Store at 2°C to 8°C. • Do not freeze. • Do not use past expiration date. • Protect from light. • Diluent may be stored at room temperature. • Reconstituted vaccine must be used as soon as possible.		
Vaccine Code	MenC-ACYW		
Antigen Code	MENING-C		
Licensed for	• Individuals 6 weeks to 55 years of age • AH has approved the use of this vaccine for eligible persons aged	• Individuals 2 months up to and including 55 years of age. • AH has approved the use of this vaccine for	• Individuals 9 months to 55 years of age. Although licensed for children nine months of age and older, the NACI does not

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	56 years of age and older (off-license).	eligible persons aged 56 years and older (off-license).	recommend this vaccine for children younger than two years of age. • AH has approved the use of this vaccine for eligible persons aged 56 years and older (off-license).

Notes:

- For documentation of Menveo® vaccine, record the lot number and expiry date from the secondary package (carton).

Program Notes:

- 2007 February 1 - Meningococcal Conjugate (A, C, Y, W-135) Menactra ® introduced into program for high risk groups 2-55 years of age.
- 2011 February - Meningococcal Conjugate (A, C, Y, W-135) routine school immunization program for Grade 9 students.
- 2012 January 26 - Meningococcal Conjugate (A, C, Y, W-135) for individuals at high risk 56 years of age and older.
- 2015 February 2 (AHS says 2015 January 1) - Menveo® Meningococcal Conjugate (A, C, Y, W-135) for high risk children 2 months to 23 months of age at high risk for invasive meningococcal disease.
- 2015 February 10 - Menactra®/Menveo® updated indication for individuals with acquired complement deficiency on Solaris®.
- 2017 September - Nimenrix® Meningococcal Conjugate (A, C, Y, W-135) was introduced into immunization program.
- 2022 August 10 - Outbreak Control added to Post-Exposure Schedule section.
- 2023 August 16 - Updated to clarify that immunization for outbreak control may continue beyond the closure of an outbreak when recommended by the Chief Medical Officer of Health.

Historical Notes:

- 1983 May 4 - 2012 January 18 - Meningococcal polysaccharide quadrivalent A, C, Y, W-135 vaccine (Menomune®) for high-risk groups.
- 2000 February 15 - 2002 March 1 - Meningococcal Polysaccharide (A, C, Y, W-135) – Outbreak campaign.
- 2001 February 6 - 2002 March 1 - Meningococcal Polysaccharide Bivalent A, C (Outbreak campaign for individuals 2-24 years of age).

Related documents:

- Meningococcal (Groups A, C, W-135 and Y) Conjugate Vaccine Information Sheet (104504).

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14. Pfizer Canada Inc. (2022 Oct 26). NIMENRIX®: Meningococcal Polysaccharide Groups A, C, W-135 and Y Conjugate Vaccine. Product Monograph.
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