Family Nursing & Home Care	**Family Nursing & Home Care** Patient Group Direction Administration of **Meningococcal ACWY conjugate vaccine** Brand name Menveo® or Nimenrix®	**PGD No: 8** Issue Date: 25.09.2017 Review Date: JUNE 2020

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by the organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Division/Department: Child & Family Service

1. Clinical Condition:

1.1	Define situation/condition	Indicated for the active immunisation of individuals, detailed in the inclusion criteria, against Neisseria meningitidis group A, C, W and Y in accordance with the recommendations given in Chapter 22 *of Immunisation Against Infectious Disease:* The Green Book.
1.2	Criteria for inclusion	Individuals who are: • eligible for routine MenACWY immunisation i.e. whole birth cohort in school year 9 and/or 10 as per national recommendations and local delivery of concurrent adolescent immunisations including Td/IPV • eligible for routine MenACWY conjugate vaccine, i.e. born on or after 1 Sep 1996 and until their 25th birthday, who have missed the routine vaccination offering in year 9 or year 10, and have unknown or incomplete MenACWY vaccination history (Note: this includes individuals in catch-up cohorts) • aged 10 years to less than 25 years with an incomplete or unknown MenC vaccination history • a close contact of a confirmed case of *Neisseria meningitidis* group A, C, W or Y disease • in a cohort recommended MenACWY immunisation following a local outbreak of *Neisseria meningitidis* and specific advice from Public Health England and the local Preventative Programmes Team • valid consent has been given to receive the vaccine (see FNHC Consent Policy re consent by children and young people http://www.fnhc.org.ie/media/42585/consent-policy-2015.pdf)

1.3	Criteria for exclusion	• Individuals for whom no valid consent has been received
		• Individuals who:
		  • have had a confirmed anaphylactic reaction to a previous dose of the vaccine
		  • have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine, including diphtheria toxoid, CRM 197 carrier protein (Menveo®),

		tetanus toxoid (Nimenrix®) • have previously received MenACWY conjugate vaccine when over 10 years old, with the exception of contacts of confirmed *Neisseria meningitidis* group A, C, W or Y infection • are at increased risk of invasive meningococcal infection, ie with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment i.e. eculizumab) – see Men.ACWY Risk Groups PGD • require vaccination for occupational health reasons e.g. laboratory workers working with meningococci • require vaccination for the purpose of travel • For full details/information of contraindications, refer to the marketing authorisation holder's SPC available at: http://www.medicines.org.uk **Temporary exclusion** • are suffering acute severe febrile illness – postpone immunisation until patient has fully recovered. (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)
1.4	Cautions/warnings	• Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. • Patients with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding – discuss with the Clinical Lead for Immunisation before taking this action. • Store between +2°C to +8°C. • Store in original packaging in order to protect from light. • Do not freeze. • Immunological response may be diminished in individuals receiving immunosuppressant treatment. This is not a reason to withhold vaccination but the patient/their carer should be advised. • Meningococcal vaccines can be given at the same time as other vaccines such as the pneumococcal conjugate vaccine, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio, Hib and HPV where indicated. • Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. • Each brand of vaccine uses a different carrier protein and the healthcare professional should refer to the SPC supplied with the vaccine if there has been a previous hypersensitivity reaction to vaccination.

		• Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. • Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated virus or bacterial vaccines or toxoids. • For full details/information of interactions, cautions and warnings, refer to the marketing authorisation holder's SPC available at: http://www.medicines.org.uk
1.5	Action if patient excluded	• Individuals who have received MenACWY conjugate vaccine over the age of 10 years do not routinely require further MenACWY immunisation with the exception of contacts of confirmed Neisseria meningitidis group A, C, W or Y infection. Contacts should be offered an appropriate meningococcal sero-group containing vaccine if not received in the preceding 12 months. • Individuals who are at increased risk of invasive meningococcal infection, i.e. with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment i.e. eculizumab), should be vaccinated in accordance with recommendations in Chapter 7 of Green Book (see MenACWY Risk Groups PGD). • In case of postponement due to acute severe febrile illness advise when the patient may be vaccinated and ensure another appointment is arranged. • Seek appropriate advice from the Specialist Nurse for Immunisation, the Clinical Lead for the Immunisation Programme or the individual's GP as required. • The risk to the patient of not being immunised must be taken into account. • Document reason for exclusion and any action taken in patient's clinical records and on the consent form. • Inform or refer to the GP or prescriber as appropriate. • Where applicable, advise when the vaccine may be given. • Arrange for further appointment if needed. • Refer to Clinical Lead for the Immunisation Programme as applicable.
1.6	Action if patient declines	• Informed consent, from the patient or a person legally able to act on the patient's behalf, must be obtained for each administration. • Advise individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. • Advise to contact Community Nurse, Immunisation Nurse Specialist or GP if wishes to discuss further in the future.

		• Document any advice given and the decision reached in the child's clinical records (EMIS) where there is refusal at the point of delivery. • Inform or refer to the GP as appropriate. • Inform Child Health Department for their database via a report generated through EMIS.

2. Characteristics of Staff

2.1	Class of Health Professional for whom PGD is applicable	Jersey Registered Nurse employed by Family Nursing & Home Care.
2.2	Additional requirements considered relevant to the medicines used in the PGD	• Has undertaken appropriate training for working under PGD's for the supply and administration of medicines • Has successfully completed the PGD e-Learning package. • Must have access to a current copy of the *Immunisation against infectious disease* ("The Green Book") and comply with its recommendations (see DH Website – www.dh.gov.uk/greenbook). • Has current training in the administration of vaccines, contraindications and the giving of appropriate advice. • Has undertaken annual practical training in paediatric basic life support and completed the e.learning training and assessment in the recognition and treatment of anaphylaxis. • All staff administering paediatric vaccines will have undertaken an initial course designed for this purpose. • Must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), *Immunisation against infectious disease* "the Green Book" and national and local immunisation programmes. • Must be competent in the handling and storage of vaccines and management of the "cold chain". • Must have access to the Patient Group Direction and associated online resources.
2.3	Continued training requirements	• Anaphylaxis training and paediatric basic life support training update yearly. • Successfully complete the FNHC PGD e.learning training every 3 years • Is in regular receipt of UK Department of Health (DH) 'Vaccine Update' which is published monthly to provide immunisers with DH information regarding changes to the childhood schedule. • Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. N.B. the most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

3. Description of Treatment

3.1	Name of Medicine and pharmaceutical form(s)	Meningococcal ACWY conjugate vaccine: **Menveo®**, 0.5ml reconstituted vaccine solution containing: Originally contained in powder vial: Meningococcal group A oligosaccharide[1] 10micrograms Originally contained in the solution vial: Meningococcal group C oligosaccharide[1] 5 micrograms Meningococcal group W135 oligosaccharide[1] 5 micrograms Meningococcal group Y oligosaccharide[1] 5 micrograms [1]conjugated to *Corynebacterium diphtheriae* CRM_{197} protein Or **Nimenrix®**, 0.5ml reconstituted vaccine solution containing: Originally in powder: *Neisseria meningitidis* A polysaccharide[2] 5 micrograms *Neisseria meningitidis* C polysaccharide[2] 5 micrograms *Neisseria meningitidis* W135 polysaccharide[2] 5 micrograms *Neisseria meningitidis* Y polysaccharide[2] 5 micrograms [2]conjugated to tetanus toxoid carrier protein 44 micrograms Solvent for solution for injection in pre-filled syringe
3.2	Legal Status	Prescription Only Medicine (POM).
3.3	Licensed or Unlicensed	Licensed *Off-Label Use* • Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 of "The Green Book" – (See section 3.7) • Menveo® is off-label for children under 2 years of age. Nimenrix® is licensed from 6 weeks of age for a schedule with a two month interval between doses, but a one-month interval is in accordance with the advice in Chapter 22 of "The Green Book". Either vaccine is recommended in accordance with the advice in Chapter 22 of "The Green Book". • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
3.4	Dose(s)	**Aged 12 months and over** Single 0.5ml dose of either Menveo® or Nimenrix® vaccine. Note: Unless they are confirmed to have been immunised against the relevant meningococcal sero-group within the preceding 12 months, vaccination should be offered to close contacts of any age.
3.5	Frequency	**Aged 12 months and over** Single 0.5ml dose of either Menveo® or Nimenrix® vaccine.

3.6	The maximum total dose or number of times treatment can be administered, and over what period of time	Single dose of 0.5ml.
3.7	Route/Method of Administration	• The MenACWY vaccines must be reconstituted in accordance with the manufacturers' instructions prior to administration. • Following reconstitution, MenACWY conjugate vaccine should be given as a single 0.5ml dose by intramuscular injection, preferably in the deltoid region of the upper arm. • The MenACWY conjugate vaccines must not be given intravascularly or intradermally. • For individuals with a bleeding disorder, vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4) – before taking this action, discuss first with the Clinical Lead for the Immunisation programme. • When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. • The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect before reconstitution and following reconstitution prior to administration. In the event of either being observed, discard the vaccine. • After reconstitution, the vaccine should be used immediately. However, stability after reconstitution has been demonstrated for 8 hours below 25°C (below 30°C for Nimenrix®). Discard any reconstituted vaccine not used within 8 hours. • The SPCs for Menveo® and Nimenrix® provide further guidance on reconstitution and administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk
3.8	Side effects (to include potential adverse reactions) and any monitoring required	**Menveo®** The most common adverse reactions observed after administration of Menveo® vaccine are drowsiness, malaise, headache, nausea, irritability and injection site pain, erythema and induration. Fever, chills, nausea, vomiting, diarrhoea, eating disorders, myalgia, arthralgia and rash are also listed as common side effects. **Nimenrix®** The most common adverse reactions observed after administration of Nimenrix® vaccine are drowsiness, fatigue, headache, loss of appetite, irritability, fever and injection site pain, erythema and swelling. Gastro-intestinal symptoms (including nausea, vomiting and

		diarrhoea) and injection site haematoma are also listed as common side effects. For full details/information on possible side effects/adverse reactions, refer to the marketing authorisation holder's SPC which is available from the Medicines Compendium website: www.medicines.org.uk All children will be observed for a few minutes after the vaccination if they are in any way unwell.
3.9	Written/Verbal advice for patient/carer before/after treatment	• Prior to appointment, consent forms and information leaflet to be sent out to parent/legally responsible adult and valid consent obtained • Parent/guardian(if present)/young person asked to confirm well at time of injection and no adverse reaction to previous doses. • Nurse to check consent with the parent/guardian(if present)/young person before the vaccine is given. • Inform of possible side effects and their management. If the parent/guardian/young person is concerned, they should be referred to their GP/Paediatrician for further discussion. • Give parent/guardian/young person the patient information leaflet • Menveo® or Nimenrix® will only confer protection against *Neisseria meningitidis* group A, C, W and Y. The vaccine will not protect against any other *Neisseria meningitidis* groups. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis infection. • To seek medical attention in the case of severe adverse reaction. • When applicable, advise when the subsequent dose is due. • When administration is postponed advise when to return for vaccination.
3.10	Procedure for reporting ADRs to Doctor	• All suspected reactions (including any considered not to be serious) should be reported to the MHRA via the yellow card system at www.yellowcard.gov.uk following discussion with the Clinical Lead for immunisation. • Parents/guardians should be made aware that they should contact either the Community Nurse, Immunisation Nurse Specialist or GP if they are worried about their child during the week after their vaccination. Any worries after that time should be discussed with their GP • The nurse may need to arrange to see the child or discuss/refer the problem to his/her GP if the reaction is outside the normal range of expected reaction • Document details of all contacts/observations in patient's Child Health Record • In the event of a severe adverse reaction requiring attendance at hospital, a letter giving details of event should be sent with the child. The nurse giving the vaccination will retain the

		responsibility to report the reaction to the MHRA.
3.11	Specify method of recording of supply/administration	• The child's consent form should be checked for its accuracy and completeness before each vaccination. This will include checking and entering new details for address and GP when necessary. • The details of the presenting child should be checked with the parent/guardian(if present)/young person. • The parent held record (red book), if presented, should be checked for details of a previous vaccination reaction. • The parent/guardian (if present) will be asked to add his/her child's vaccination dates to the Parent Held Child Health Record (Red Book) • Following immunisation, relevant information will be returned to the administration office of Public Health within 7 days. • The details of the vaccination will be entered onto the Child Health computer by Public Health Administration. • The following details must be recorded: o Name of the child being vaccinated o Date of birth of the child o Name and brand of vaccine o Dose given o Date of vaccination o Batch number and expiry date o Route of administration o Site of administration o That a PGD was used o Information/advice given o Name and signature of vaccinator (or a password controlled immuniser's record on e-records).

Key References

Patient Group Direction (PGD) has been adapted for local use from Public Health England's PGD for the administration of the Meningococcal Group A,C,W and Y conjugate vaccine (MenACWY) available at https://www.gov.uk/government/publications/menacwy-vaccine-menveo-or-nimenrix-patient-group-direction-pgd-template (accessed 15/08/17)

MenACWY Conjugate Vaccine

Enhanced Service Specification: Meningococcal ACWY (MenACWY) 18 years on 31 August vaccination programme 2017/18. Published March 2017 https://www.england.nhs.uk/publication/enhanced-service-specifications/

Menveo® Summary of Product Characteristics. Novartis Vaccines Updated 09 October 2015 http://www.medicines.org.uk/emc/medicine/27347

Immunisation Against Infectious Disease: The Green Book, Chapter 22 last updated 20 September 2016. https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22

Meningococcal ACWY (MenACWY) vaccination programme. Published 07 November 16 https://www.gov.uk/government/collections/meningococcal-acwy-menacwy-vaccination-programme

Meningococcal Disease: Guidance, Data and Analysis. Published 28 August 2015 https://www.gov.uk/government/collections/meningococcal-disease-guidance-data-and-analysis

Nimenrix® Summary of Product Characteristics. GlaxoSmithKline UK Updated 21 December 2016 http://www.medicines.org.uk/emc/medicine/26514

General

British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.bnf.org https://www.evidence.nhs.uk/formulary/bnf/current

Department of Health UK (2006 updated 2017) Immunisation Against Infectious Disease: The Green Book www.dh.gov.uk/greenbook

Department of Health UK (2017) 'Vaccine Update' published monthly to provide immunisers with information regarding changes to the UK childhood immunisation schedule, available at: https://www.gov.uk/government/collections/vaccine-update

Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336

National Health Service (2017) The routine immunisation schedule from Autumn 2017 available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/625833/Complete_Imm_schedule_2017.pdf

National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards

NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013 https://www.nice.org.uk/guidance/mpg2

NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014 https://www.nice.org.uk/guidance/mpg2/resources

Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

PHE Immunisation Collection. https://www.gov.uk/government/collections/immunisation

Public Health England/National Health Service England MenACWY (2015) bipartite letter available at: https://www.gov.uk/government/publications/menacwy-vaccine-introduction

The electronic Medicines Compendium website: www.medicines.org.uk

Yellow card adverse event reporting system available at http://yellowcard.mhra.gov.uk

Change History

Date	Change Details
2017	Updated FNHC template used Black triangle removed from Nimenrix 1.2 inclusion criteria now defined as school year rather than age as per Public Health England's template PGD for Meningococcal ACWY immunisation. Link included to FNHC Consent Policy re consent in children and young people. 1.3 statement and website link added re use of marketing authorisation holder's summary of product characteristics Immunisation not excluded in pregnancy when clinically indicated 1.4 Discussion with Clinical Lead for Immunisation required before administering vaccine to patients with a bleeding disorder Additional cautions and warnings added statement and website link added re use of marketing authorisation holder's summary of product characteristics 1.5 additional actions added giving clarity in specific circumstances 1.6 additional advice added which includes contacting other named health professionals where further discussion is required. GP and Child Health Department to be informed Statement added re informed consent 2.1 '...employed by Family Nursing & Home Care' added 2.2 section updated in line with other childhood immunisation PGDs 2.3 section updated in line with other childhood immunisation PGDs 3.1 typo corrected Constituents of vaccines detailed as per Public Health England's template PGD for Meningococcal ACWY immunisation. 3.3 off label use detailed. 3.7 additional details added as per Public Health England's template PGD for Meningococcal ACWY immunisation. Discussion with Clinical Lead for Immunisation required before administering vaccine to patients with a bleeding disorder has been added 3.8 side effects updated Statement added that all children should be observed for a few minutes after vaccination if they are in any way unwell 3.9 updated to include: action prior to the appointment; asking for confirmation that child is well at time of injection and that they have not had any adverse reaction to previous doses; nurse to explain the possibility of

	any reaction and if concerned to be referred to GP/Paediatrician, inform of side effects and management, advise to seek prompt medical attention at first signs of possible meningitis infection, advise when subsequent dose due, advise what to do when administration postponed 3.10 section standardised to be in line with other PGDs for childhood immunisations 3.11 section standardised to be in line with other PGDs for childhood immunisations however rather than recording 'manufacturer', this has been changed to 'brand' Also, 'as standard at date of delivery' has been removed from two of the points.

4. Management of Patient Group Direction:

I Developed by:		
	Name	**Signature**
Senior Doctor	Sarah Whiteman (Medical Director, Primary Care)	
Senior Pharmacist	Sara Kynicos (Pharmacy Advisor to Family Nursing & Home Care)	
Senior Health Professional	Michelle Cumming (Operational Lead for Child and Family Services)	
Other (please specify		

II Approved by CEO of Family Nursing & Home Care		
	Name	**Signature**
Chief Executive Officer	Judy Foglia (Acting Chief Executive Officer)	
Date of Approval		

III Authorised by the Minister for Health		
	Name	**Signature**
Minister for Health	Andrew Green	
PGD Number	**8**	
Date of Authorisation	25.09.2017	
Date for Commencement of Review	JUNE 2020	
Last Date for Reauthorisation	24.09.2020	

Plan a review to enable completion prior to the date above and date the new protocol to follow on immediately, also retain a copy of each version of the protocol for ten years.