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

Patient Group Direction (PGD)

For the administration or supply of

Meningococcal group A, C, W and Y (MenACWY) conjugate vaccine

By registered health care professionals for

the administration of meningococcal group A, C, W and Y (MenACWY) conjugate vaccine to individuals eligible for the national routine MenACWY vaccination programme; university freshers (catch-up); outbreak control and contacts of confirmed cases, for active immunisation against *Neisseria meningitidis*

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 95

1. Change History

Version number	Change Details	Date
01.00	New PHE PGD	10/07/15
02.00	PHE MenACWY PGD amended to: • remove specific information on individual catch-up cohorts from previous years • removal of preferred vaccine choice and related update to off-label section following changes to the Nimenrix® license • reference the protocol for ordering storage and handling of vaccines • update wording regarding authorisation in line with agreed PHE PGD template changes • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	04/05/17
03.00	PHE MenACWY PGD amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • remove the exclusion of individuals who are at increased risk of invasive meningococcal infection and redirect from the inclusion criteria to the MenACWY Risk Groups PGD where applicable • extend expiry date through to the end of the school year (end of July) • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	20/02/19
04.00	PHE MenACWY PGD amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references	14/06/21

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • 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 have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	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' and Guidance for Public Health Management of Meningococcal Disease in the UK
Inclusion criteria	• Individuals who are: • eligible for routine MenACWY immunisation, that is the 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, born on or after 1 Sep 1996 and until their 25th birthday, who have missed the routine vaccination offer 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 • prospective students up to 25 years of age who are entering university for the first time and who have not received a dose of MenACWY conjugate vaccine after their tenth birthday • Note: Vaccination should be offered before they enrol or as soon as possible thereafter, ideally at least two weeks before attending university to ensure timely protection. • 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 Health Protection Team • Note: Individuals with an underlying medical condition which puts them at increased risk from Neisseria meningitidis, such as individuals with asplenia, splenic dysfunction or complement disorders (including those on, or due to receive, complement inhibitor treatment such as eculizumab), may require additional 'routine' vaccination outside the inclusion criteria for this PGD - see MenACWY Risk Groups PGD and Chapter 7 of 'The Green Book'.
Criteria for exclusion[1]	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

[1] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

	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 • require vaccination for occupational health reasons, such as laboratory workers working with meningococci • require vaccination for the purpose of travel • are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)
Cautions (including any relevant action to be taken)	• The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed. However, re-immunisation may need to be considered. • 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.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	• Patient should be referred to a more experienced clinical practitioner for further assessment • 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 requiring vaccination for occupational health reasons, such as laboratory workers working with meningococci, should be referred to their occupational health service provider for vaccination • Individuals requiring vaccination solely for the purpose of travel are not covered by this PGD and should be referred to, or immunised as part of, a travel immunisation service. MenACWY vaccine is not available on the NHS for the purpose of travel • In case of postponement due to acute severe febrile illness advise when the individual may be vaccinated and ensure another appointment is arranged • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required • The risk to the individual of not being immunised must be

	taken into account • Document reason for exclusion and any action taken in individual's clinical records • In a GP practice setting, inform or refer to the GP or prescriber as appropriate
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

8. Details of the medicine

Name, form and strength of medicine	**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
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Indicate any <u>off-label use</u> (if relevant)	• Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in <u>Chapter 4</u> of 'The Green Book' • 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 <u>Chapter 22</u> of 'The Green Book'. Either vaccine is recommended in accordance with the advice in <u>Chapter 22</u> of 'The Green Book'

	• Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence
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 anterolateral aspect of the thigh is the preferred site for infants under one year old • The MenACWY conjugate vaccines must not be given intravascularly or intradermally and must not be mixed with other vaccines in the same syringe • 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) • 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 • It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 8 hours (see storage section) • 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

Dose and frequency	**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. **Contacts aged under 12 months** Two 0.5ml doses administered at least 4 weeks apart (see Off-label section)
Quantity to be administered	Single dose of 0.5ml (repeated at least 4 weeks later in children under 12 months of age)
Maximum or minimum treatment period	Single dose of 0.5ml(repeated at least 4 weeks later in children under 12 months of age)
Storage	• Store at +2°C to +8°C • Store in original packaging to protect from light • Do not freeze • In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to PHE Vaccine Incident Guidance
Adverse effects	**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 induration • Gastro-intestinal symptoms (including nausea, vomiting and diarrhoea) and injection site haematoma are also listed as common side effects • A detailed list of adverse reactions associated with Menveo® or Nimenrix® is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: www.medicines.org.uk • Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card

	in the Google Play or Apple App Store • Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.
Records to be kept	The administration of any medication given under a PGD must be recorded within the patients' medical records Please see Appendix C for more details.

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request • Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. • Immunisation promotional material may be provided as appropriate. • For parents of 'contact' children under 12 months: • Why is my child being offered an 'off-label' vaccine. • Available from: www.gov.uk/government/collections/immunisation
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • When administration is postponed advise the individual/carer/parent when to return for vaccination • 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 • Inform individual/parent/carer of possible side effects and their management • Give advice regarding normal reaction to the injection, for example redness and pain at the injection site • The individual/parent/carer should be advised to seek medical advice in the event of a severe adverse reaction • When applicable, advise the individual/parent/carer when the subsequent dose is due

10. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

MenACWY Conjugate Vaccine

- Nimenrix® Summary of Product Characteristics. Pfizer Ltd. Updated 23 November 2020. http://www.medicines.org.uk/emc/medicine/26514
- Menveo® Summary of Product Characteristics. GlaxoSmithKline UK. Updated February 2021 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
- Guidance for Public Health Management of Meningococcal Disease in the UK, Public Health England, published 13 March 2018, updated 06 August 2019 . https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management
- Meningococcal ACWY (MenACWY) vaccination programme 2020/2021 https://digital.nhs.uk/services/general-practice-gp-collections/service-information/meninogococcal-acwy-menacwy-vaccination-programme
- Meningococcal Disease: Guidance, Data and Analysis. Last updated 20 December 2019 https://www.gov.uk/government/collections/meningococcal-disease-guidance-data-and-analysis

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- 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
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
- Protocol for ordering storage and handling of vaccines. April 2014.

https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Special considerations/ additional information	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. 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.
Disposal	Equipment used for immunisation, including used vials, ampoules, or syringes, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Supplies	• Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for the national immunisation programme are provided free of charge. • Vaccine for the national immunisation programme should not be used for the vaccination of contacts of confirmed cases and in outbreaks of MenACWY infection. Vaccine should be ordered from the manufacturers/wholesalers. • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3)

Drug interactions	Immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of interactions associated with Menveo® or Nimenrix® is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD • Records should be signed and dated (or a password-controlled immuniser's record on e-records) • All records should be clear, legible and contemporaneous. • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed • The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy