Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare 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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

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

by registered healthcare practitioners

to

individuals with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis*

in Powys Teaching Health Board

Version number: PGD 0179C

Reference Number: PGD 0179C
Valid from: 31/07/2025
Review Date: 30/06/2027
Expiry Date: 31/12/2027

Change History

Version number	Change details	Date
PGD 0179	Initial Issue PHE template adopted	28/05/2021
PGD 0179A	Review issue in accordance with UKHSA template v04.00 MenACWY Risk Groups PGD amended to: • include particulars pertaining to an additional licensed ACWY vaccine (MenQuadfi®) • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • replace Public Health England' and 'PHE' with 'UKHSA' including branding and updated contact details	28/02/23
PGD 0179B	Review in line with UKHSA Notice of extension of the validity of the MenACWY Risk Groups PGD v4.0, pending anticipated revisions to the childhood immunisation programme and the withdrawal of Hib/MenC (Menitorix®) vaccine. **UKHSA Publications gateway number: GOV-14014** Also reviewed to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other PTHB PGDs	10/02/25
PGD 0179C	Review issue in line with UKHSA MenACWY Risk Groups PGD template v5.0 to: • take account of the changes to the childhood immunisation schedule • include minor formatting and other revisions to bring the template in line with other UKHSA PGD templates • correct spelling errors to MenQuadfi® from v4.0 • reflect updated references • include registered healthcare professionals named in HMR2012 Removal of the **Impact of changes to the childhood immunisation programme from 1 July 2025** information from the **special considerations** section of the UKHSA PGD template v5.0, following advice from VPW and WMAS that this section does not apply to Wales.	31/07/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v5.0 developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy (also ratified by the UKHSA Medicines Governance Committee).

The UKHSA template has been adapted for use in PTHB.

Developed by the following health professionals on behalf of the UKHSA:

Developed by:	**Name**
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Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation Programmes, UKHSA

Expert Panel:

Name	**Designation**
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Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
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Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Elizabeth Luckett	Senior Screening & Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHSE South East
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	7/28/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	7/29/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	7/29/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	8/6/2025

The PGD is not legally valid until it has had the relevant organisational authorisation. It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. Appendix A provides a staff accreditation sheet. **Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.**

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Info.MedicinesManagement.Powys@wales.nhs.uk

[1] This includes any relevant amendments to legislation.

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

Qualifications and professional registration	**All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below**. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC) Check Appendix A- Staff Accredited to use the Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. Must have completed eLfH PGD eLearning Patient Group Directions training (available via learning@wales, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A) • 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 and online training. Please contact PTHB immunisation co-ordinator for further information • 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. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the intramuscular injection technique • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Basic Life Support skills • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Updating at least every 2 years on the administration of meningococcal groups A, C, W, and Y conjugate vaccine (MenACWY). 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). Practitioners must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Compliance with all mandatory NHS training (if relevant). Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and/or the UKHSA, NHS England (NHSE) and other sources of medicines information. Note: 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis* groups A, C, W and Y, in accordance with the recommendations given in Chapter 7 and Chapter 22 of Immunisation Against Infectious Disease: the Green Book. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	Individuals who: • are at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction, or complement disorders (including those on, or due to commence complement inhibitor treatment, such as eculizumab (Soliris®) and ravulizumab (Ultomiris®) Note: This includes individuals with medical conditions accompanied by functional hyposplenism (such as sickle cell disease), but does not include those with coeliac disease unless concurrent hyposplenism has been diagnosed. • Medical and drug history taken, no reason for exclusion • Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).

Criteria for exclusion[2]	Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine, including diphtheria toxoid, CRM_{197} carrier protein (Menveo®) and tetanus toxoid (Nimenrix® and MenQuadfi®) • have received MenACWY conjugate vaccine over 1 year of age and in the last 12 months (excluded as they are adequately immunised) • are not at increased risk of invasive meningococcal infection and require routine MenACWY vaccination • are a contact of an individual diagnosed with *Neisseria meningitidis* groups A, C, W and Y disease. • 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 infection is not a contraindication for immunisation) Refer to sections "action to be taken if the individual is excluded" and "action to be taken if the individual or carer declines treatment".
Cautions, including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with national recommendations. Where possible, vaccines should be administered 2 weeks before immunosuppressive treatment begins, before immunosuppression occurs, or deferred until an improvement in immunity is seen. 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

[2] 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

	is important that procedures are in place to avoid injury from faints. Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list). Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Action to be taken if the individual is excluded	Individuals who have had a confirmed anaphylactic reaction to a previous dose of the vaccine or any of its components should be referred to a clinician for specialist advice and appropriate management. Individuals who have received MenACWY conjugate vaccine over one year of age and in the last 12 months do not require a further dose of MenACWY conjugate vaccine when diagnosed at risk. Individuals who are not at increased risk of invasive meningococcal infection and require routine MenACWY vaccination or who are a contact of *Neisseria meningitidis* groups A, C, W and Y disease, should be vaccinated in accordance with UKHSA recommendations (see MenACWY PGD 0094). 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 private travel immunisation service. MenACWY conjugate 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 can be vaccinated and ensure another appointment is arranged at the earliest opportunity. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or PTHB Infection Control Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Explain reason to individual / carer. Inform or refer to the individual's GP or a prescriber as appropriate.
Action to be taken if the individual or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. The patient information leaflet should be available to inform consent. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document the advice given and the decision reached. Inform or refer to the individual's GP or a prescriber as appropriate. Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Meningococcal groups A, C, W and Y conjugate vaccine, MenACWY: **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 or **MenQuadfi®**, 0.5ml solution for injection containing: • *Neisseria meningitidis* group A polysaccharide[3] 10 micrograms • *Neisseria meningitidis* group C polysaccharide[3] 10 micrograms • *Neisseria meningitidis* group W polysaccharide[3] 10 micrograms • *Neisseria meningitidis* group Y polysaccharide[3] 10 micrograms [3] conjugated to tetanus toxoid carrier protein 55 micrograms
Legal category	Prescription only medicine (POM)
Black triangle▼	MenQuadfi®· As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product.

	All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.
Off-label use	Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 of the Green Book. Menveo® is off-label for children under 2 years of age, as is MenQuadfi® for children under 12 months. Nimenrix® is licensed from 6 weeks of age, for a schedule with a minimum 2 month interval between doses, but a one month interval is in accordance with the advice in Chapter 22 of the Green Book. Where possible, administer a vaccine licensed for the age of the individual. If no licenced vaccine is available, then an alternative vaccine may be given off-label to avoid undue delay. All vaccines are recommended in accordance with advice in Chapter 7 and Chapter 22 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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and 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, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but outside of product licence.
Route and method of administration	MenACWY conjugate vaccines should be given as a single 0.5ml dose by intramuscular injection, preferably into the deltoid muscle of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under one year old. See Green book chapter 4. The MenACWY conjugate vaccines must not be given intravascularly or intradermally and must not be mixed with other vaccines in the same syringe. 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. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccine or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre, such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in the Green Book Chapter 4. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures. The SPCs for Menveo®, Nimenrix® and MenQuadfi® provide further guidance on preparation and administration.
Dose and frequency of administration	**Individuals first diagnosed or presenting under one year of age** Individuals, with asplenia, splenic dysfunction or complement disorders, should receive: • 2 primary doses of MenACWY vaccine at least 4 weeks apart during their first year, and • one booster dose of MenACWY vaccine after the first birthday Where possible, the course should be completed with the same brand of MenACWY vaccine. However, vaccination should not be delayed and any of the licensed vaccines may be used. **Individuals first diagnosed or presenting over one year of age.**

	Individuals over one year of age, with asplenia, splenic dysfunction or complement disorders, require a single dose of MenACWY vaccine on presentation, at least 4 weeks after vaccination with Hib/MenC (as applicable to individuals born on or before 30 June 2024). Refer to the Green Book Chapter 7 for a practical schedule for immunising individuals with asplenia, splenic dysfunction or complement disorders, which takes into account the other vaccines required by these individuals.
Duration of treatment	See dose and frequency of administration section above
Quantity to be administered	Single dose of 0.5ml per administration
Supplies	Vaccine for the national immunisation programme should not be used for the vaccination of at-risk individuals. Vaccines should be ordered from the manufacturer or their wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines
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, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.

	After reconstitution of Menveo® and Nimenrix®, 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. MenQuadfi® and Nimenrix® stability data indicate the unopened vaccine may be used up to 72 hours following exposure to temperatures up to 25°C. See the respective SPC for further information. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	The immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited. MenACWY vaccine may be given at the same time as other vaccines. A detailed list of drug interactions associated with Menveo®, Nimenrix® and MenQuadfi® are available from the product's SPC.
Identification and management of adverse reactions	**Menveo®** The most common adverse reactions observed after administration of Menveo® vaccine are drowsiness, malaise, headache, 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, irritability, fever and injection site pain, erythema and induration and loss of appetite. Gastro-intestinal symptoms (including nausea, vomiting and diarrhoea) and injection site haematoma are also listed as common side effects.

	MenQuadfi® The most common adverse reactions observed after administration of MenQuadfi® vaccine are malaise, headache, myalgia and injection site pain. Fever and injection site induration and erythema are also listed as common side effects. A detailed list of adverse reactions associated with Menveo®, Nimenrix® and MenQuadfi® are available from the product's SPC. Report any suspected adverse reactions to a doctor. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis:- • Refer to adrenaline (epinephrine) PGD 0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO Meningococcal groups A, C, W, and Y conjugate vaccine (MenACWY) and state the BRAND of vaccine administered** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the using the Yellow Card reporting scheme or by searching 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. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.
Written information to be given to individual or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home – Health Publications. Immunisation promotional material may be provided as appropriate: • Splenectomy leaflet

	Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site Immunisation and Vaccines - Public Health Wales, Public Health Wales Immunisation and Vaccine Preventable Disease Programme and NHS 111 Wales. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.
Advice and follow up treatment	Menveo®, Nimenrix® or MenQuadfi® will only confer protection against *Neisseria meningitidis* groups 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 or septicaemia. Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of a severe adverse reaction and report this via the Yellow Card reporting scheme. When applicable, advise the individual, parent or carer when a subsequent dose is due. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination. Medical conditions such as coeliac disease, sickle cell disease and other haemoglobinopathies may be accompanied by functional hyposplenism. However, hyposplenism in coeliac disease is uncommon in children, and the prevalence correlates with the duration of exposure to gluten. Therefore, individuals diagnosed with coeliac disease early in life and well managed are unlikely to require additional MenACWY vaccine. Only those with known splenic dysfunction should be vaccinated in accordance with this PGD. Individuals receiving complement inhibitor therapy (for example, eculizumab, ravulizumab) are at heightened risk of meningococcal infection and should be vaccinated with both MenACWY and MenB vaccines (see MenB Risk Groups PGD 0199), ideally at least 2 weeks prior to commencement of therapy.

	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 breastfeeding with inactivated virus or bacterial vaccines or toxoids. Each brand of vaccine uses a different carrier protein and the healthcare professional should refer to the SPCs supplied with the vaccine if there has been a previous hypersensitivity reaction to vaccination.
Records	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • medical and drug history taken, including any allergies and previous adverse events • printed name and signature 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 • any reasons for exclusion or referral, including actions taken • advice given, including advice received from medical cover and/or advice given if excluded or immunisation declined • details of any adverse drug reactions and actions taken • administered via PGD, record PGD title and number 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. When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Services team (CHIS) or Child Health Department using the appropriate documentation or pathway as required by any local or contractual arrangement

	(based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age). A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	MenACWY conjugate vaccine

- Nimenrix® Summary of Product Characteristics. Pfizer Ltd, updated 18 December 2024. http://www.medicines.org.uk/emc/medicine/26514
- Menveo® Summary of Product Characteristics. GlaxoSmithKline UK, updated 14 March 2025 https://www.medicines.org.uk/emc/medicine/27347
- MenQuadfi® Summary of Product Characteristics. Sanofi, updated 19 December 2024 https://www.medicines.org.uk/emc/product/12818/
- Immunisation Against Infectious Disease: The Green Book, Chapter 22, last updated 17 May 2022 and Chapter 7, last updated 10 January 2020 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Changes to routine childhood and selective neonatal hepatitis B vaccinations (WHC/2025/019) https://www.gov.wales/childhood-vaccination-schedule-whc2025019-html

General

- NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
- National Minimum Standards and Core Curriculum for Immunisation Training. Published 7 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 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources
- UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation
- Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration.

	https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017 • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste. 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments "	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.